# VitaGuard® VG 3100

# Apnea, heart, and $SpO_2$ monitor

## Operating instructions

getemed

# Who should read which sections in these operating instructions?

The sections **3** to **8** colored blue at the top of the page and in the table of contents are intended specifically for caregivers without medical background knowledge.

The other sections are intended in particular for doctors and qualified medical staff.


1 General view and list of accessories

2 Intended use

3 Safety

4 Description

5 Steps before and after monitoring

6 Preparing for $SpO_2$ monitoring

7 Preparing for heart rate and apnea monitoring

8 Alarms, displays, and views during monitoring

9 Alarm and monitor settings

10 Information for the doctor and qualified medical staff

11 Algorithms and measuring principles

12 Evaluating stored data on a PC

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**NOTE Words and passages in SMALL CAPITALS in these operating instructions also appear on the display.**

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# 1 General view and list of accessories

The general view shows the monitoring system's most important components.

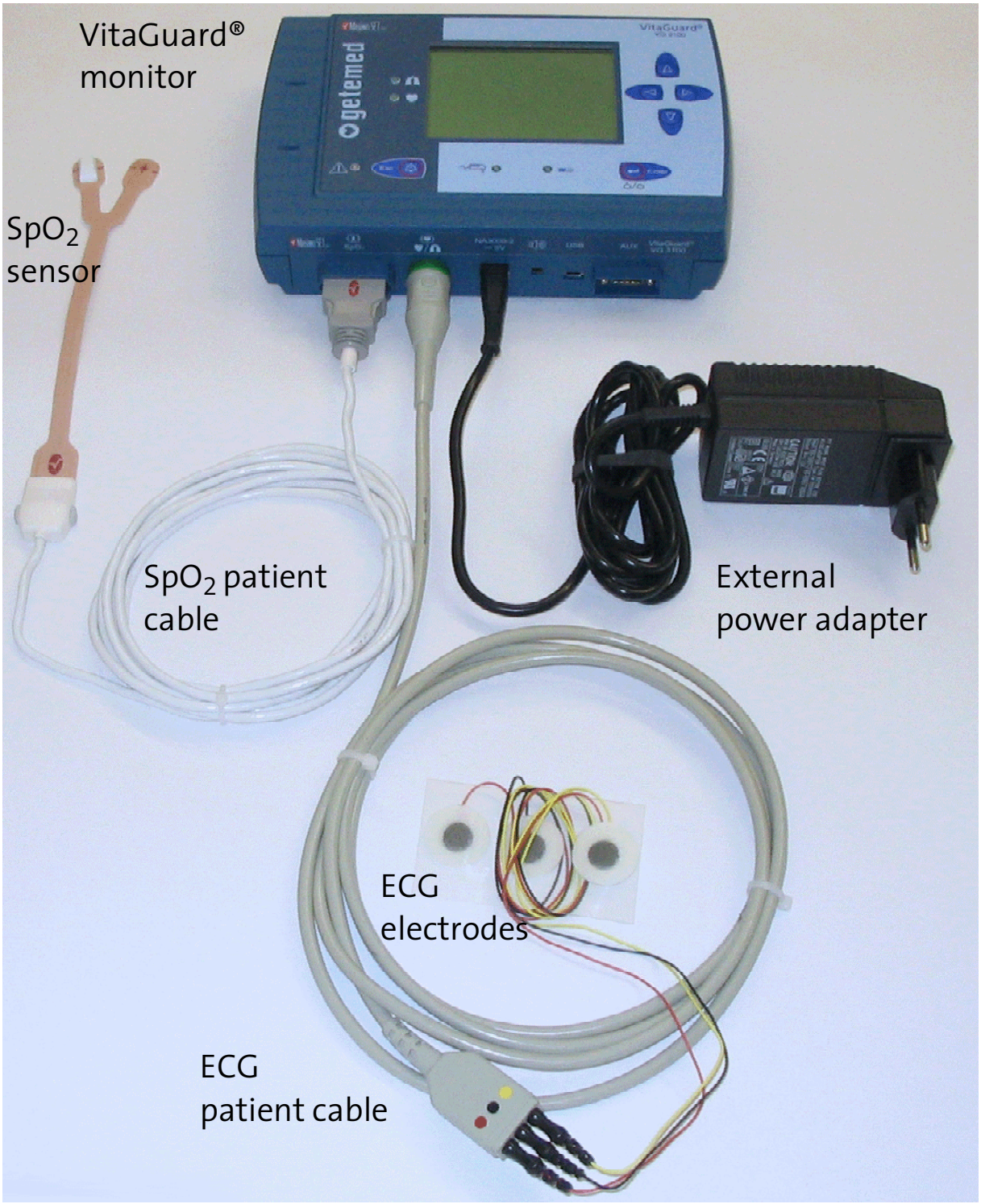



*Fig. 1 General view of the monitoring system*

The accessories listed in the following can be used together with VitaGuard® and can be ordered with the specified article numbers from getemed AG or authorized dealers. Please consult getemed AG or your authorized dealer for other approved accessories.

**Product ..... Article no. / REF**

VitaGuard® VG 3100 Monitor (with Masimo SET®),
complete system ..... 7311 2012

1 VitaGuard® VG 3100 monitor
1 ECG patient cable, 9 neonatal electrodes
1 PC08 $SpO_2$ patient cable
1 $SpO_2$ LNOP Neo sensor incl. spare adhesive strip
1 NA3000-2 external power adapter
1 rechargeable block battery
1 device bag
1 operating instructions, 1 quick reference
Transport case

NA 3000-2 external power adapter
(110 V–240 V~ / 50–60 Hz) ..... 7344 1101

NAK 3000-2 automobile power supply adapter ..... 7344 1201
Rechargeable block battery ..... 7344 2201

PK1-8P ECG patient cable ..... 7341 1001

Kitty Cat™ neonatal electrodes (PU = 30 pcs) ..... 70222

Masimo PC08 $SpO_2$ patient cable (2.44 m) ..... 70257

Masimo LNOP® NeoPt $SpO_2$ sensor (PU = 20 pcs)
(for one patient use only, infants < 1 kg) ..... 70250

Masimo LNOP® Neo $SpO_2$ sensor (PU = 20 pcs)
(for one patient use only, infants < 10 kg) ..... 70251

Masimo LNOP® Pdt $SpO_2$ sensor (PU = 20 pcs)
(for one patient use only, pediatric/ slender finger 10–50 kg) . 70252

Masimo LNOP® Adt $SpO_2$ sensor (PU = 20 pcs)
(for one patient use only, adult > 30 kg) ..... 70253

Masimo LNOP® DCI reusable sensor (> 30 kg) ..... 70254
Masimo LNOP® DCIP reusable sensor (10–50 kg) ..... 70264

Other models are available in addition to the $SpO_2$ sensors listed here.

Operating instructions (English) ..... 7381 2021
Alarm chart (English) ..... 7383 1021

Operating instructions (German) ..... 7381 2011
Alarm chart (German) ..... 7383 1011

Operating instructions (Turkish) ..... 7381 2081
Alarm chart (Turkish) ..... 7383 1081

Device bag ..... 7345 1001
VitaGuard® transport case (for the complete system) ..... 7391 0001

AUX 01 RS232 cable for connecting VitaGuard®
to a serial PC port ..... 7341 2002

AUX-02 modem cable for connecting a
modem to VitaGuard® ..... 7341 3001

AUX-03 cable for connecting an external alarm unit
to VitaGuard® ..... 7341 5001

AUX-04 cable for connecting VitaGuard®
to a nurse call system with 4 kV isolation ..... 7341 5011

AUX-06 cable for connecting two external signal sources
to VitaGuard® ..... 7341 6001

# 2 Intended use

This section provides information on the intended use of VitaGuard® and the limitations of this intended use.

**CAUTION Do not attempt to use VitaGuard® for detecting obstructive apneas. Obstructive apneas, i.e. respiratory arrest following an occluded respiratory tract, are not detected by VitaGuard®. Food debris or vomit, for example, can occlude the respiratory tract.**

**The doctor treating the patient is responsible for the application of VitaGuard®. The specific "Information for the doctor and qualified medical staff" can be found on page 99.**

**getemed AG recommends qualified training for the caregivers in potentially necessary resuscitation techniques. Clearing the respiratory tract and the resuscitation of babies and infants require particular know-how that the treating doctor should communicate to the caregivers.**

## 2.1 Label on the back of the device

The device label serves as a unique identifier for VitaGuard®. In addition, the label bears important cautionary information.

On the device label you will find the manufacturer's name and address as well as the product and model name. The serial number of your device is given next to SN.

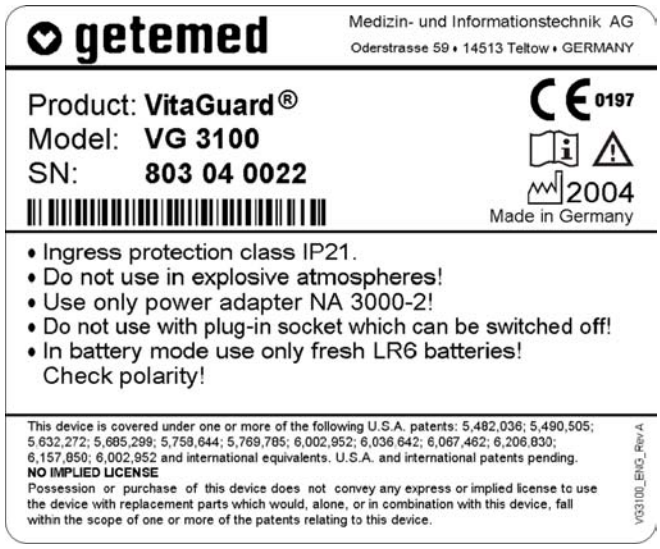

getemed
Medizin- und Informationstechnik AG
Oderstrasse 59 • 14513 Teltow • GERMANY
Product: VitaGuard®
Model: VG 3100
SN: 803 04 0022
CE 0197
2004
Made in Germany
• Ingress protection class IP21.
• Do not use in explosive atmospheres!
• Use only power adapter NA 3000-2!
• Do not use with plug-in socket which can be switched off!
• In battery mode use only fresh LR6 batteries! Check polarity!
This device is covered under one or more of the following U.S.A. patents: 5,482,036; 5,490,505; 5,632,272; 5,685,299; 5,758,644; 5,769,785; 6,002,952; 6,036,642; 6,067,462; 6,206,830; 6,157,850; 6,002,952 and international equivalents. U.S.A. and international patents pending.
NO IMPLIED LICENSE
Possession or purchase of this device does not convey any express or implied license to use the device with replacement parts which would, alone, or in combination with this device, fall within the scope of one or more of the patents relating to this device.
VG3100_EKG_Rev A

*Fig. 2 Device label on the bottom of the device*

## 2.2 Symbols and warnings

This symbol warns you that failure to observe these operating instructions can cause death or injury to the patient.

The book symbol means that you must not use the device when you are not familiar with the information contained in these operating instructions.

With this CE label and the CE approval number 0197 getemed AG confirms that VitaGuard® complies with all the pertinent regulations and in particular the requirements in Annex I of the Medical Devices Directive 93/42/EWG and that this has been approved by a notified body (TÜV Rheinland Product Safety).

This symbol means that the VitaGuard®'s ECG socket is a type CF (cardio floating) application part and that it is protected against the effects of defibrillation.

This symbol means that the VitaGuard®'s $SpO_2$ socket is a type BF (body floating) application part that is protected against the effects of defibrillation.

The factory symbol shows the year of manufacture.

Note the warnings on the device label.

**Do not use in explosive atmospheres!**

**Use the NA 3000-2 power adapter only!**

**Warning: Do not connect to an electrical socket controlled by a wall switch!**

**Only new alkaline batteries (LR6 or AA) must be used when the device is powered by non-rechargeable batteries! Note the polarity!**

## 2.3 Indications

VitaGuard® can be used to monitor patients with, for example, the following symptoms or treatment:

- unstable respiration
- oxygen therapy
- life-threatening cardiac dysrhythmia
- conspicuous sleep laboratory findings
- facial and/ or cervical and thoracic dysmorphia
- distinct gastro-esophageal reflux
- ataxia

### 2.3.1 $SpO_2$ and pulse rate monitor

The $SpO_2$ and pulse rate monitor with the attached accessories is suitable for the permanent, non-invasive monitoring of arterial blood oxygen saturation ($SpO_2$) and of the pulse rate as measured with the $SpO_2$ sensor. The functional blood oxygen saturation displayed as $\%SpO_2$ is determined exclusively from the measurements of oxygenated and deoxygenated hemoglobin.

The $SpO_2$ and pulse rate monitor is suitable for adult, pediatric, and infant patients, in mobile or stationary indoor and outdoor applications, including patients with weak blood flow and those in hospitals and other institutions.

### 2.3.2 Heart rate and apnea monitor

The heart rate and apnea monitor is suitable for adult, pediatric, and infant patients at home or in rooms used for medical purposes.

The apnea monitor is specifically intended for monitoring central apneas. Successful apnea monitoring requires a stable underground and a patient that lies quietly without moving.

## 2.4 VitaGuard® modes of operation

Depending on the risk group and the latest diagnosis, VitaGuard® allows the treating doctor to combine three monitoring parameters:

- $SpO_2$ monitoring
- heart or pulse rate monitoring
- apnea monitoring

The doctor can deactivate the apnea monitor in the RESPIRATION menu, or combine the apnea monitor alarms with the heart rate and oxygen saturation monitor. In this case, apnea alarms are triggered only when, after detecting apnea, the device also detects deviations from particular average values in the monitored heart rate and/ or the monitored $SpO_2$. This combination helps to reduce false apnea alarms.

When VitaGuard® is to be used to monitor heart rate and respiration only, the doctor can deactivate the $SpO_2$ monitor in the $SpO_2$ menu.

In addition to the fixed alarm limits for the heart or pulse rate monitor and the $SpO_2$ monitor, the doctor or the qualified medical staff can also configure percentage deviations as alarm conditions.

The doctor or the qualified medical staff can find all other explanations they may need in the following sections:

- “Settings in the $SpO_2$ menu (SETTINGS PROTECTION OFF)” on page 121,
- “Settings in the HEART RATE menu (SETTINGS PROTECTION OFF)” on page 123,

- “Settings in the RESPIRATION menu (SETTINGS PROTECTION OFF)” on page 129,
- “Combining apnea alarms with heart rate and $SpO_2$ alarms” on page 130,
- “Table of operating modes” on page 131.

**In the event of electrode allergies it may prove convenient, after consultation with the treating doctor, to dispense with the electrodes entirely for a time and to operate the device as a pulse oximeter. The display then shows the PULSE RATE monitored by the $SpO_2$ sensor instead of the HEART RATE.**

## 2.5 Intended use and performance

The intended use of VitaGuard® is to detect central apneas when the patient is completely immobile on a stable underground and to monitor the heart or the pulse rate as well as the oxygen saturation. VitaGuard® is designed for applications at home and in rooms used for medical purposes. VitaGuard® has no therapeutic effect.

VitaGuard® emits an acoustic and visual alarm when no respiration or movement is detected within a set period, when the measured heart rate and/or oxygen saturation values violate the set alarm limits for a period also set by the operator, and/or when no heartbeat has been detected for a set period. The alarm limits can be set within particular values specified by VitaGuard®.

Respiration and heart rate are monitored with adhesive ECG electrodes and blood oxygen saturation and pulse rate with an $SpO_2$ sensor suitable to the patient’s age and weight.

VitaGuard® determines the heart rate from the ECG signal detected by the electrodes and the pulse rate from the signal detected by the $SpO_2$ sensor. The doctor can choose whether the pulse or the heart rate is used for alarm triggering.

VitaGuard® features an impedance monitor that triggers a technical alarm when an electrode exhibits impedance values that are not compatible with proper operation. This is the case, for example, when an electrode has become detached.

When the signal registered by the $SpO_2$ sensor is inadequate for the reliable measurement of values, a message appears on the display.

Physiological data measured for a set period before and after an alarm are stored and can afterwards be evaluated and documented.

VitaGuard® can be operated with the NA3000-2 power adapter (9 V), the NAK3000-2 automobile power adapter (e.g. in the cigarette lighter), four non-rechargeable batteries, or a rechargeable block battery. Non-rechargeable batteries or the rechargeable block battery serve above all to safeguard the monitor's functions during a power failure and to continue monitoring the heart rate and oxygen saturation when patients are in transit.

## 2.6 Limitations on VitaGuard®'s intended use

**Even when operated in accordance with its intended use, VitaGuard® cannot detect all life-threatening situations under certain unfavorable conditions.**

### 2.6.1 Obstructive apneas are not detected

Obstructive apneas are not detected by VitaGuard®. The caregiver may have to remove food debris from the patient's oral cavity.

When an obstructive apnea at the same time triggers a bradycardia alarm (heart rate too low) or an oxygen saturation alarm ($SpO_2$ value too low), resuscitation measures may need to be taken.

### 2.6.2 Limitations of the heart rate and central apnea monitor

VitaGuard® could misinterpret movements as respiration, e.g. in ambulances, cars, and prams or when a child is held in the arms. For this reason central apneas can be detected only when the patient is sleeping or is lying still, does not move, and is not being moved.

The heart rate can be monitored with electrodes also when the patient is moving, but sudden, vigorous movements can adversely affect the measuring accuracy.

A false heart rate is displayed during ventricular fibrillation or when the heart rate exceeds 270 beats per minute.

### 2.6.3 Limitations of the $SpO_2$ and pulse rate monitor

The monitoring of $SpO_2$ and pulse rate is adversely affected when the patient moves vigorously or is vigorously moved.

When the sensor is not attached correctly, ambient light can falsify measurements. One remedy is to cover the sensor with a dark or opaque material.

The monitor operates properly only when the $SpO_2$ sensor is correctly attached.

## 2.7 Information for the doctor on these operating instructions

**In full knowledge of these operating instructions, the treating doctor must decide:**

- whether the caregivers have to be trained in the performance of resuscitation measures,
- how the caregivers can be best prepared for monitoring and above all for the measures that must be taken in the event of an alarm,
- which view should be displayed

Information on SETTINGS PROTECTION that sets the display modes and user configurations can be found on page 91.

“Information for the doctor and qualified medical staff” is found on page 99.

# 3 Safety

**The doctor decides whether the caregivers are able to use VitaGuard® for monitoring and whether they can implement appropriate measures in the event of an alarm.**

## 3.1 Caregivers' tasks

With "caregivers" we mean those persons who are responsible during monitoring for the monitored patient's well-being, for example:

- parents or other members of the family,
- babysitters, when they too have been thoroughly prepared for the situation,
- nurses and other medically trained staff.

**Observe in particular the information in those sections of the operating instructions that, like here, address you directly.**

**Observe the extensive safety instructions at the beginning of the section "Preparing for $SpO_2$ monitoring" on page 51.**

**Observe the extensive safety instructions at the beginning of the section "Preparing for heart rate and apnea monitoring" on page 61.**

**VitaGuard® has no therapeutic effect. You may have to implement resuscitation measures in the event of an alarm.**

**The potential applications of VitaGuard® for high-risk patients are so many and diverse that we are unable to give any specific instructions on procedure in the event of an alarm. It is the doctor's task to inform high-risk patients and their caregivers in detail on the correct procedure in this case.**

**An alarm chart is available from getemed AG when monitoring children. This alarm chart presents a sequence of activities that are considered suitable by many medical specialists and pediatricians.**

Do not attempt to use VitaGuard® on more than one patient at a time.

Never modify settings without consulting the responsible doctor. Only the doctor knows the correct alarm limits and monitor configuration for each patient.

Never leave the patient's room without first making sure that the LEDs for heart and respiration are flashing.

Make absolutely sure that you can react to an alarm within a few seconds. Move away from patients only so far that you can reach them within ten seconds.

When you are not sure that VitaGuard® is in perfect operating order, check the patient's vital functions. Under no circumstances should you use VitaGuard® when you suspect a device defect.

In the event of ANY suspected VitaGuard® malfunction, continue to observe the patient until you can use a replacement monitor, or VitaGuard® has been examined by the doctor or authorized dealer.

Stop using VitaGuard® after the servicing interval of eighteen months has expired. Before the end of this period, make an appointment with your authorized dealer to check the safety and operability of your device.

Test the acoustic alarm unit every time you switch on VitaGuard®. This is explained in the section "Alarm test" on page 69.

CAUTION! When attaching the electrodes make sure that the plugs do not touch any other electrically conducting parts. Make sure that there can also be no contact with other electrically conducting parts when the electrodes become detached during monitoring.

Treat all leads and connections with particular care, and never use the connecting cables to lift VitaGuard®.

Switch off VitaGuard® before boarding an aircraft. When you want to transport VitaGuard® in your luggage, you should remove the batteries. This prevents other pieces of luggage from switching on

**the device by accident. An activated, but disconnected VitaGuard® will generate acoustic alarm signals.**

## 3.2 Allergy risks to patients

**Attach ECG electrodes and $SpO_2$ sensors to intact areas of skin only.**

**So that the permanent contact with the electrodes does not put too much of a strain on the patient's skin, the electrodes can be placed in the vicinity of the optimal site.**

All materials that are used with VitaGuard® and can come into contact with patient or caregivers during normal operations are free of latex and are non-toxic in accordance with the standard ISO 10993-1.

getemed AG recommends replacing the adhesive electrodes used to monitor heart rate and apnea as soon as they start to lose their adherence. The special gel for the electrodes has been developed to avoid skin irritation, even after several months' monitoring on newborns.

Nevertheless, patients with sensitive skin may suffer allergic reactions in the form of reddened skin and blistering that in serious cases may look like burns. When the skin exhibits such changes, you must immediately inform the doctor. A change of electrode type may help.

The use of $SpO_2$ sensors with adhesive materials may cause problems when the patient develops an allergy to adhesive tape or similar.

## 3.3 Possible external interference to monitoring

**Please bear in mind the possibility of other risks that are not listed here that can be caused by your specific monitoring environment.**

### 3.3.1 Installation and environment

We recommend hanging VitaGuard® in the delivered bag at a place where the display can be easily viewed.

Check, as described in the section “Alarm test” on page 69, that you can hear alarms and where you can hear them. Think also of the activities that cause noises, for example showering or vacuuming. Think before you raise the volume of your television or stereo. Also, the VitaGuard®’s alarm outlet should not be obstructed by any objects that absorb sound.

Never place VitaGuard® or the power adapter such that they could fall on the patient. For example, the power adapter could become detached from an overhead socket when the cable is pulled.

Do not immerse either VitaGuard® or the accessories in liquids.

Variations in temperature and air humidity could lead to condensation forming in and on VitaGuard®. Wait for at least two hours after VitaGuard® has visibly dried on the outside before using it for monitoring.

Do not operate VitaGuard® in environments containing explosive gases, flammable substances, nitrous gases, or highly oxygen-enriched atmospheres. Do not use VitaGuard® at extreme temperatures below 5 °C or above 40 °C. Do not place VitaGuard® near heat sources such as radiators, ovens, etc. Do not expose it to direct sunlight.

Always lay all cables and in particular any extension cables so that nobody can trip over them.

Do not place VitaGuard® directly next to the patient’s head: risk of hearing damage!

### 3.3.2 Noise risks to monitoring

When the alarm cannot be set to a volume that is sufficiently above the prevailing ambient noise levels, you must keep VitaGuard® and

**its display within view. The visual signals from the alarm LED and display must then be relied upon to recognize critical situations.**

You can also use the external alarm unit available from getemed AG that raises the volume of the alarm signals from VitaGuard®.

Information on the alarm signal types and volumes can be found in “Alarms, displays, and views during monitoring” on page 69. The alarm pitch is set as explained in the section “SYSTEM menu – general settings” on page 89.

### 3.3.3 Electrostatic interference

**Electrostatic build-up that, for example, a person can pick up on certain carpets must not discharge through the VitaGuard® connector sockets or the electrodes’ electrically conducting parts.**

**For this reason, avoid touching the electrically conducting parts, or discharge any electrostatic build-up beforehand by, for example, touching an earthed water pipe or heater.**

### 3.3.4 Electromagnetic interference

**VitaGuard® is not designed for applications near strong electromagnetic fields. These interference fields are frequently emitted by devices with large electric power consumptions. Keep a good distance from e.g. washing machines, computers, microwaves, vacuum cleaners, power tools, etc.**

**The device and the system can be used in the home and in all other environments that public utilities supply directly.**

**Bear in mind that portable and mobile HF communication devices, e.g. cellular phones, radio equipment, walkie-talkies, etc., can interfere with the monitor and influence its operability.**

**Bear in mind that non-approved accessories can amplify emitted interference and reduce the device’s immunity.**

**Do not place the monitor directly next to other electrical equipment, and do not stack monitors on top of each other.**

**When the monitor has to be placed next to or on other equipment, check that the monitor operates as designed in this environment. We recommend you to check at regular intervals:**

**– that the displayed signals are not disrupted when the patient is not moving,**
**– whether the same technical alarm messages are repeatedly displayed.**

**When you discover disruptions:**
**– if possible, switch off the interfering equipment or move this equipment to another site.**

**VitaGuard® uses high-frequency signals exclusively for its internal functions. As a result, its emitted interference is very low, and disruption to neighboring electronic equipment is unlikely.**

**False diagnoses are possible when monitored values are corrupted by interference from electric or electromagnetic fields and this escapes the doctor's attention. Every time you analyze stored data, consider the possibility of interference from electric or electromagnetic fields.**

VitaGuard®'s emitted interference and immunity to external interference are within the limits for life-supporting systems stipulated in the standard EN 60601-1-2.

## 3.4 Safety with approved accessories only

**Use VitaGuard® only with the delivered or approved accessories and in accordance with the information contained in these and the accessories' operating instructions.**

**Electrodes, $SpO_2$ sensors, cables, and power adapters can be ordered from your authorized dealer or directly from getemed AG. The telephone number of your authorized dealer was given to you during**

your training on how to operate the device, or it is found on a label your authorized dealer has attached to VitaGuard®.

Bear in mind that monitoring can continue without interruption only as long as the required consumables are available. In emergencies of this nature you can call your authorized dealer, who provides 24-hour emergency services. Please try, however, to avoid unnecessary stress for both yourself and your authorized dealer, and order your consumables in good time.

The modem used to transfer monitoring data must comply with the requirements under the German and European standard DIN EN 60950 “Safety of IT Equipment” with the amendments A1–A4. These details are found in the modem’s operating instructions.

## 3.5 Handling patient cables

Always lay patient cables at a good distance from the patient’s head and neck. Lay each patient cable inside the clothing, and secure it in place in such a way that no harm can come to the patient or cable (strangulation, twisting).

Make sure when laying and securing patient cables that these cannot kink (kinking causes damage).

For hygiene reasons, always use the same patient cable on the one patient. Disinfect patient cables before using them on a new patient.

When more than one monitor is used in the one environment, each monitor should always be connected to the same patient cables and the same power adapter. Faults can therefore be located and remedied faster.

## 3.6 Power supply reliability

Before first using VitaGuard® for monitoring, familiarize yourself with the section “Power supply” on page 36. Monitoring is safeguarded only when the power supply is in perfect operating order.

CAUTION: Danger of electric shock! Never open the external power adapter or the connecting cable.

Exclusively the NA 3000-2 approved for VitaGuard® must be used as the external power adapter.

VitaGuard® is usually delivered with the external power adapter for European supply networks. For other supply networks, use only the plug adapters available from getemed AG.

Do not use the external power adapter in sockets that can be switched off or dimmed.

When the VitaGuard® external power adapter is plugged into a multiple socket outlet, only the modem may be connected to this outlet simultaneously.

When an extension cable is used with a multiple socket outlet, this outlet must not lie on the floor. Otherwise water may penetrate the outlet and damage the monitor.

The external power adapter and the power outlet must be free of damage.

Never use the external power adapter’s cable to lift VitaGuard®.

Stop using the external power adapter when it has fallen or been dropped.

Do not operate the external power adapter in a damp environment (e.g. in the bathroom).

Always leave the batteries in VitaGuard®, even when this is operated through the external power adapter.

**VitaGuard® operates with batteries: either non-rechargeable batteries or a rechargeable block battery. VitaGuard® must be operated only with the rechargeable block battery available from getemed AG or new alkaline non-rechargeable 1.5 V batteries (LR6 or AA), e.g. VARTA UNIVERSAL ALKALINE. Bear in mind that cheaper non-alkaline non-rechargeable batteries can have a considerably reduced operating lifetime, in some cases only 10–15% of the brand name batteries we recommend.**

**Do not under any circumstances use single rechargeable batteries available on the market.**

**Never use a non-rechargeable battery and a rechargeable battery together in the device, and never mix old and new batteries.**

**To prevent leaking batteries from damaging health and property, remove non-rechargeable batteries from VitaGuard® when it is not used for longer than a week. Information on “Replacing batteries” can be found on page 38.**

### 3.6.1 Battery voltage indicator

**When VitaGuard® is powered only by non-rechargeable batteries, check the battery voltage indicator on the display every hour. At least one quarter of the battery symbol must be black.**

*Fig. 3 Battery voltage indicator*

**When VitaGuard® is powered from the supply network and commercially available non-rechargeable batteries are inserted, check the battery voltage indicator on the display every day. Even when the device is powered from the supply network, you must replace the non-rechargeable batteries as soon as one quarter of the battery symbol on the display is black.**

If necessary, a display message will prompt you to insert new non-rechargeable batteries or to recharge the block battery.

### 3.6.2 Interruptions to the power supply

When the external power adapter is connected VitaGuard® operates automatically in supply network mode. When the supply network fails, VitaGuard® switches automatically to battery mode – when batteries are inserted.

As long as VitaGuard® is powered from the external power adapter or the automobile power supply, the green LED next to the power adapter symbol lights up.

Normal voltage fluctuations in the supply network do not adversely affect monitoring with VitaGuard®. Following a power supply failure, the current alarm settings are retained for at least thirty days and are again available when the device is switched back on.

### 3.6.3 Using the rechargeable block battery

Note the warnings on the rechargeable block battery's label.

**Do not open or short-circuit!**

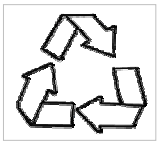
**Do not throw into a fire!**

**Avoid temperatures over 50 °C!**

The charging time for the block battery is at most six hours.

*Fig. 4 Rechargeable block battery*

Also note the recycling symbol on the label. This means that the block battery must be recycled when its service life has expired.



**Do not expose the block battery to direct sunlight. For example, temperatures greater than 50 °C can easily occur on a vehicle's dashboard or rear shelf.**

When you intend to use VitaGuard® powered from the rechargeable battery block and disconnected from the supply network, you must first make sure that the block battery is fully charged. For this reason, check the “Battery charging” LED. The battery is being charged as long as this LED light is continuously on. When the LED flashes every second, the battery is full and compensation charging is activated.

Sometimes the light will go out for a short time in the interval between battery and compensation charging.

## 3.7 Safety with proper maintenance only

VitaGuard® can operate safely and reliably over the long term only when it is subject to proper maintenance and use.

Check visually for any damage on VitaGuard®, the patient cables including the connections, the external power adapter, the electrodes, and the $SpO_2$ sensor every time you use VitaGuard® for monitoring.

Every eighteen months at the latest VitaGuard® and accessories must be serviced by getemed AG to comply with safety regulations.

Repairs must be performed by getemed AG only. Clarify the necessary procedure with your authorized dealer.

For the protection of our service personnel, disinfect VitaGuard® and the patient cables with Virkon®, available as a spray or wiping solution, before sending them to getemed AG.

### 3.7.1 Cleaning VitaGuard® and accessories

Before cleaning VitaGuard®, remove the batteries.

Before cleaning VitaGuard®, detach the electrodes and cables from the monitor and from the patient.

**Do not under any circumstances use solvents like ether, acetone, or benzene. These substances can cause malfunctions and attack the housing plastic.**

**Also, do not use any cleaning agents containing abrasive substances and no coarse brushes or hard objects.**

**VitaGuard® and accessories can be cleaned any number of times when the recommended cleaning agents are used.**

**VitaGuard® and accessories must not be sterilized.**

**VitaGuard® and the cable plugs must not be immersed or otherwise penetrated by liquid.**

Cleaning the exterior is best done with a non-linting cloth moistened slightly with water or a mild soap solution.

getemed AG recommends disinfecting the device with Virkon®, available as a spray or wiping solution.

Patient cables can be cleaned with liquid Cable Care or with a 70% alcohol solution. Baby oil has proved to be effective in removing residue from adhesive strips.

The VitaGuard® bag can be washed by hand at 30 C. It must not be put in the laundry dryer.

### 3.7.2 Checking and cleaning the battery terminals

**Check the battery compartment every month for traces of leaking and for deposits on the battery terminals indicating leaks. Contact your authorized dealer and clarify further procedures when a battery starts to leak.**

The battery compartment and how to replace the batteries are explained in the section “Replacing batteries” on page 38.

## 3.8 Disposing of non-rechargeable batteries, the device, and accessories

getemed AG takes back all of the parts it delivers. For hygiene reasons these parts do not extend to consumables like electrodes and sensors that have been in direct contact with the patient.

**The symbol of the crossed-out waste container on the battery packaging is to remind you that under no circumstances must you dispose of batteries in normal household waste. As the end consumer you are legally obliged to return used batteries or dispose of them properly. You can return used batteries to us.**

**Place consumables like electrodes and sensors in a plastic bag before disposing of them in household waste.**

**Please do NOT send us ANY used electrodes or sensors.**

Like every electronic device, VitaGuard® and accessories contain metal and plastic parts that must be disposed of in such a way that they do not pollute the environment after their service live. For this reason, the device and accessories may be sent to getemed AG in an adequately stamped package, when possible in the original packaging, for free and proper disposal.

# 4 Description

**We recommend placing VitaGuard® in the bag provided. This bag protects the monitor and can be hung from a site where it cannot fall.**

*Fig. 5 VitaGuard® and bag with power and patient cables*

## 4.1 Power supply

**VitaGuard® is usually delivered with the power adapter for European supply networks. For other supply networks, contact getemed for the appropriate plug adapter. Observe the information in “Power supply reliability” on page 29.**

*Fig. 6 Power adapter socket*

VitaGuard® is normally supplied by the power adapter (Fig. 7, left) in the 230 V/ 50 Hz supply network.

The NAK3000-2 automobile power supply adapter (Fig. 7, right) for vehicle dashboards can be inserted in this socket.

*Fig. 7 Power adapter for 230 V/ 50 Hz supply network and automobile power supply*

When VitaGuard® is supplied by the external power adapter, the green LED lights up next to the power adapter symbol. In addition, the display backlight is activated when VitaGuard® is switched on.

When VitaGuard® is supplied by the power adapter only, without inserted batteries, a display message will prompt you to insert batteries.

When VitaGuard® is supplied by the power adapter, charging of the inserted rechargeable block battery is activated. The LED next to the battery symbol illuminates.

### 4.1.1 Power failure with inserted batteries

VitaGuard® automatically switches to battery mode when the external power supply fails or the power adapter is disconnected. In this event a technical alarm is permanently emitted until the power supply has been reinstated or the <Esc> key pressed.

When the supply network LED is off, but you can still see the usual monitor displays, VitaGuard® is being supplied by the batteries.

### 4.1.2 Power failure without batteries

VitaGuard® is fitted with an internal battery. This provides the voltage for an acoustic signal that is emitted when monitoring cannot be continued during a power failure.

The acoustic alarm from the internal battery does not stop until VitaGuard® has been switched back on after the power adapter has been reconnected or batteries have been inserted.

A power failure jeopardizes monitoring when

- the batteries in the VitaGuard® are nearly depleted or
- no batteries have been inserted and VitaGuard® is disconnected from the external power adapter.

To stop the power draw on the internal battery, it is important that non-rechargeable batteries are inserted as quickly as possible or, better, the power adapter is reconnected.

**VitaGuard® must not be used for monitoring when the internal battery is depleted. This status appears on the display.**

A new internal battery can be installed at getemed AG only, so you must continue monitoring with a replacement device until the internal battery has been displaced.

### 4.1.3 Replacing batteries

**Switch off VitaGuard® before replacing batteries.**

Push back the catch and lift off the battery cover to open the battery compartment. Insert either four non-rechargeable batteries or the rechargeable block battery.

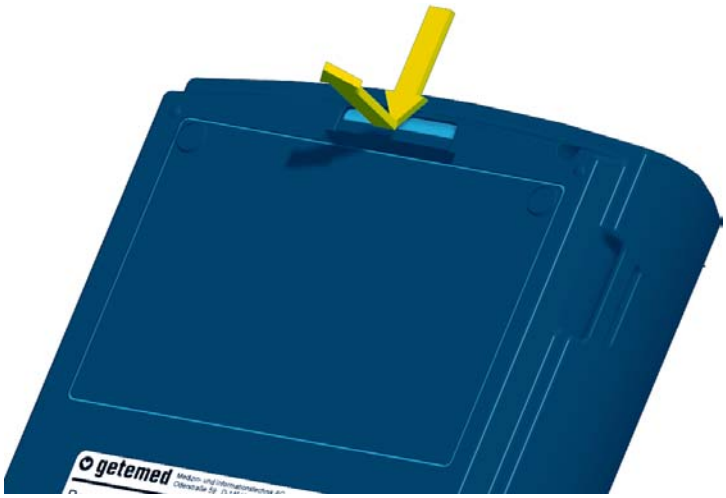



*Fig. 8 Opening the battery compartment*

**Make sure that the + symbols on the batteries and in the compartment match before inserting non-rechargeable batteries.**

*Fig. 9 Opened battery compartment and polarity*

**Observe the following instructions when you use the rechargeable block battery.**

- Never use force to insert the block battery.
- The bottom of the block battery has a guide groove that prevents the battery from being inserted the wrong way. Make sure when inserting the block battery that the labeled side is on the top and the metal terminals point to the device label.

- You will feel a slight pressure from the terminal spring connections when inserting the block battery.

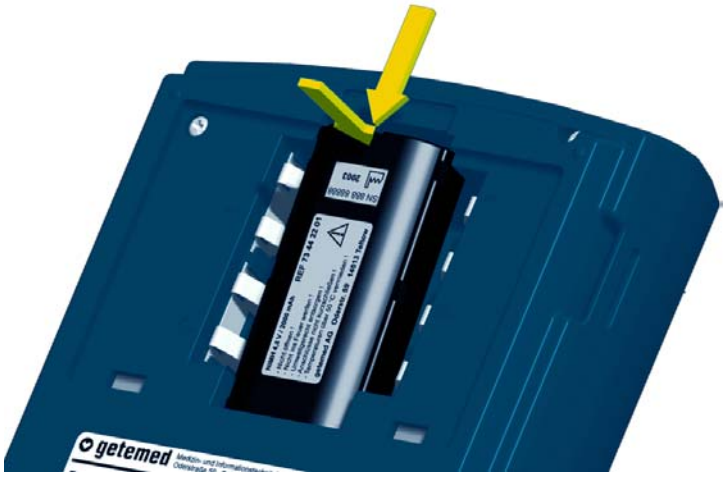



*Fig. 10 The arrows show how the block battery is correctly inserted.*

### 4.1.4 Using the automobile power supply adapter

**Use only the NAK 3000-2 automobile power supply adapter to operate VitaGuard® from a vehicle's dashboard.**

**Do not leave the automobile power supply adapter overnight in the vehicle (particularly during the cold season). Otherwise condensation may form on and in the device.**

The NAK 3000-2 automobile power supply adapter is connected to the VitaGuard® power adapter socket. NAK 3000-2 features a universal safety plug (DIN ISO 4165) for the dashboard lighter. Automobile power supply mode is indicated on VitaGuard® by the green LED beside the power adapter symbol.

The specifications of the automobile power supply adapter are as follows:

| | |
|---|---|
| Input | Automobile voltage supply at 12–24 V |
| Output | 9 Vdc |
| Max current | < 500 mA |
| Operating temperature | +5 to +50 °C |
| Connection to VitaGuard® | 3-pin plug |
| Connection to automobile supply | Universal safety plug (DIN ISO 4165) |
| Connecting cable length | 2 m ± 20 cm |

## 4.2 VitaGuard® connections

*Fig. 11 Overview of VitaGuard® connections*

**For safety reasons, only those accessories that getemed AG has delivered or approved must be connected to VitaGuard®.**

**Hold VitaGuard® firmly with one hand when connecting and disconnecting plugs.**

**Never use force when connecting and disconnecting cables. Always insert and remove the plugs parallel to the sockets to prevent damage to the sensitive contacts.**

**Only the doctor, in full knowledge of the information under “Connections to the USB and AUX ports” on page 101, must decide which devices are connected to the USB and AUX ports.**

### 4.2.1 Patient cable for $SpO_2$ sensors

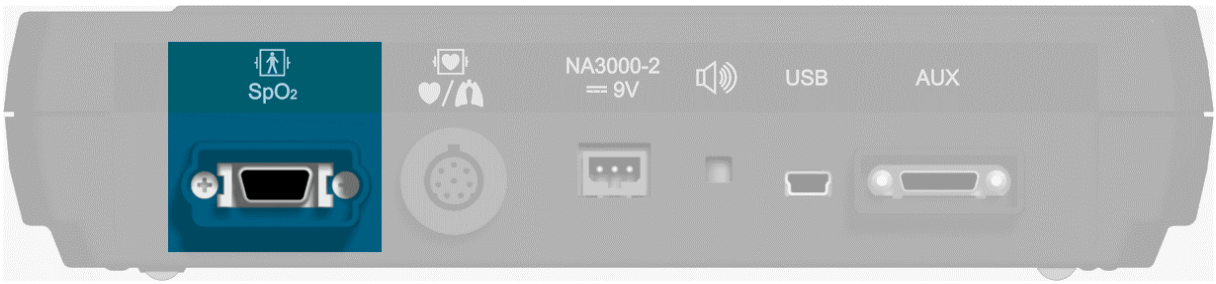



*Fig. 12 $SpO_2$ socket*

The patient cable for the $SpO_2$ sensors is connected to the $SpO_2$ socket.

### 4.2.2 Patient cable for electrodes

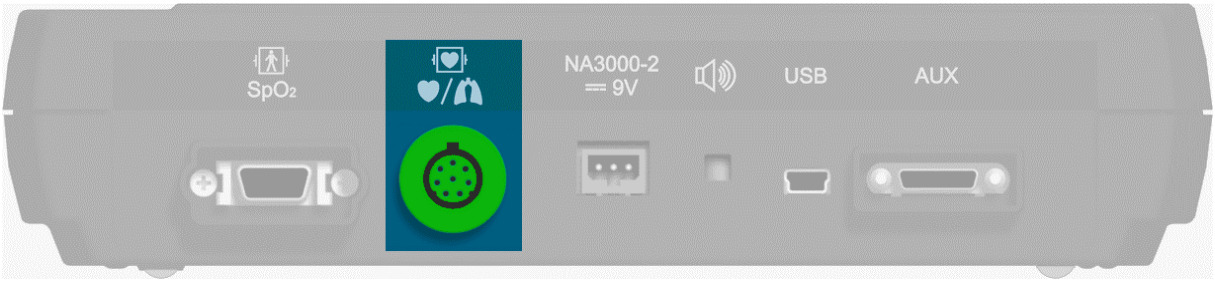



*Fig. 13 Electrode socket*

The patient cable for the electrodes for heart rate and apnea monitoring is connected to this socket.

### 4.2.3 Power adapter

*Fig. 14 Power adapter socket*

The external power adapter socket is for connecting the NA 3000-2 external power adapter or the NAK 3000-2 automobile power supply adapter.

### 4.2.4 Sound outlet (no socket)

*Fig. 15 Sound aperture*

The outlet in the figure is not a socket, but a sound hole for the internal system monitor buzzer.

**This outlet emits a pulsating sound when the external power adapter is disconnected from the monitor and no batteries are inserted.**

The sound outlet is located between the cable sockets so that it cannot be covered by objects such as cushions or curtains.

### 4.2.5 USB port

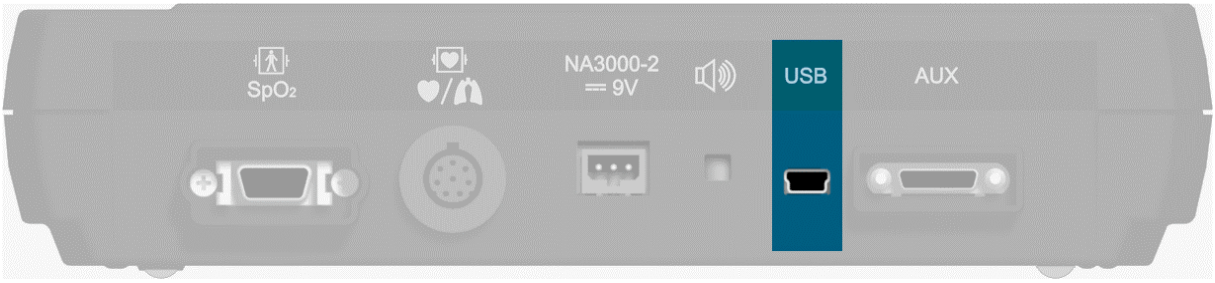



*Fig. 16 USB port*

The USB (universal serial bus) port serves to read out stored data and to modify the VitaGuard® settings via a PC.

### 4.2.6 AUX port

*Fig. 17 AUX port*

The AUX (auxiliary) port can take the following connections:

- Two analog inputs
- Modem for communicating data
- Nurse call unit
- External alarm unit

**VitaGuard® cannot confirm whether an alarm signal has been reported by a nurse call unit. As explained in the section “Alarm test” on page 69, check each time you switch on the device that an alarm signal is really transferred and the alarm reported.**

**Measure the time it takes for an alarm to be reported and the time needed to reach the patient. No more than ten seconds must pass between these times. Observe the operating instructions for the nurse call unit.**

## 4.3 Membrane key panel

**Do not apply excess pressure to the keys.**

VitaGuard® recognizes key presses only when the keys have been pressed for about one second.

There are six membrane keys on the top side of VitaGuard®.

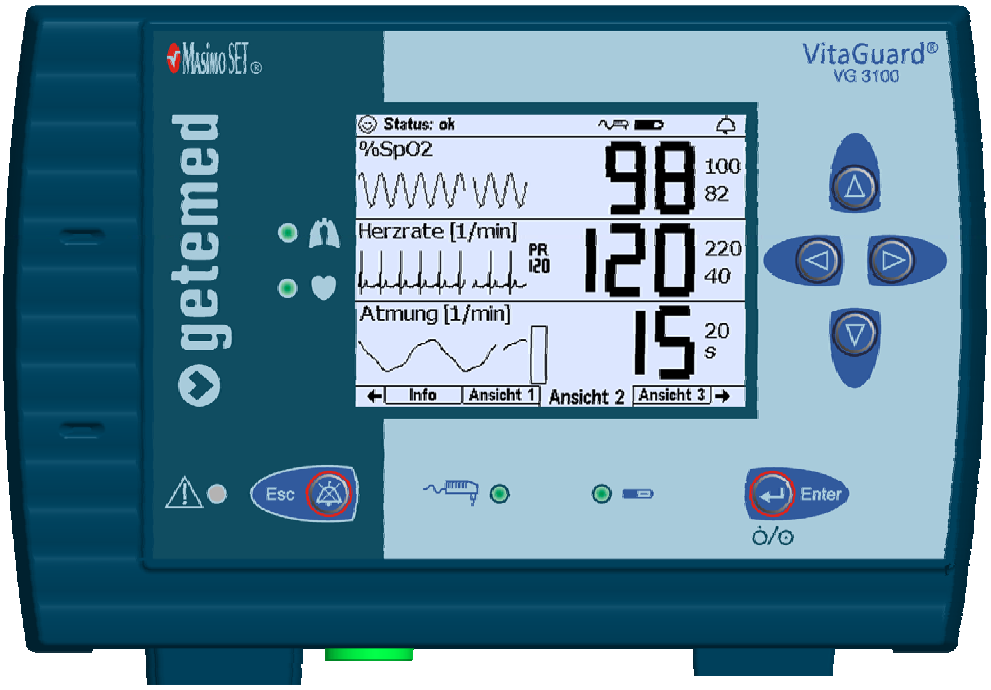



*Fig. 18 Keys on the top side*

### 4.3.1 Direction keys

With the direction keys you navigate from one window to the next.

The direction keys also allow you to navigate within the menu structure.

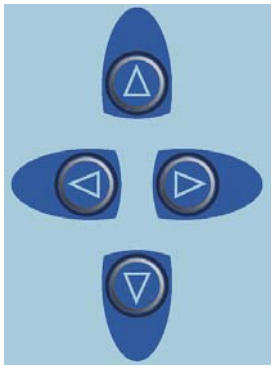


*Fig. 19 Direction keys*

### 4.3.2 <Enter> key

- The <Enter> key switches VitaGuard® on and off.
- The <Enter> key also lets you confirm changes to the monitor settings.

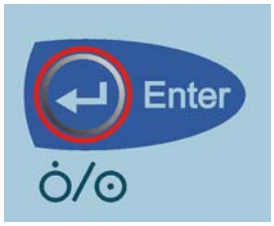



*Fig. 20 <Enter> key*

### 4.3.3 <Esc> key

- When an alarm is triggered, the <Esc> key serves to deactivate the acoustic alarm signal for a set alarm mute time. During an alarm condition the red alarm LED and the violated alarm limit flash. The acoustic alarm is again emitted if the alarm condition persists after the alarm mute time has expired. Pressing the <Esc> key during the alarm mute time a second time reactivates the acoustic alarm.

*Fig. 21 <Esc> key*

- Also when an alarm has automatically ended (because the vital functions have restabilized by themselves) the alarm LED and the violated alarm limit continue to flash until you press the <Esc> key. The alarm LED, however, flashes slower than during an alarm.

- The <Esc> key cancels unsaved changes to the monitor settings or moves back to the next-higher menu.

## 4.4 Color LEDs (Light Emitting Diodes)

When VitaGuard® is switched on, all LEDs light up for a short time so that you can see they work properly. During this time, the alarm LED first lights up red and then yellow.

### 4.4.1 Alarm LED

- In the event of a higher-priority alarm, i.e. a physiological alarm, the alarm LED flashes red.
- In the event of a medium-priority alarm, i.e. a technical alarm, the alarm LED flashes yellow.

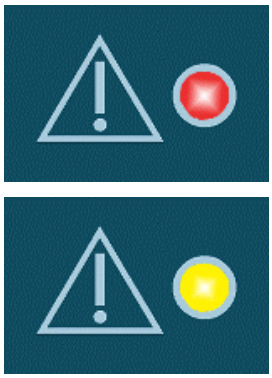


*Fig. 22 Alarm LED*

### 4.4.2 Heart and respiration LEDs

The LED with the heart symbol flashes with every heartbeat of the patient. In other words, this LED flashes as fast as the heart beats.

The LED with the lungs symbol lights up with every detected breath of the patient when the patient does not move and is not moved. In other words, this LED flashes as fast as the patient breathes.

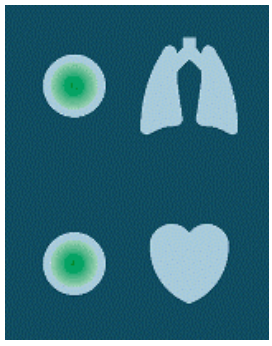


*Fig. 23 Heart and respiration LEDs*

These two flashing green LEDs show you even in complete darkness that monitoring is activated.

Also, the SYSTEM menu lets you switch on and off an acoustic signal that is emitted synchronously with the heartbeat or respiration.

### 4.4.3 Power supply and battery LEDs

- When the LED with the power adapter symbol lights up, VitaGuard® is being powered from the supply network or an automobile power supply.

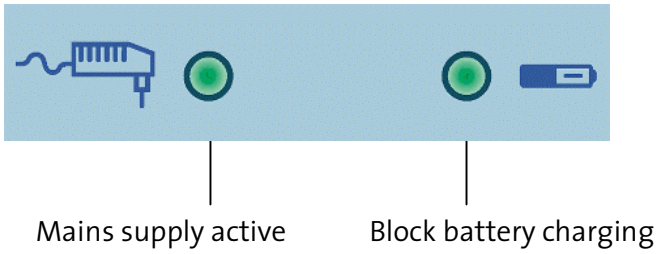



*Fig. 24 Power supply LEDs*

- When the LED with the power adapter symbol does not light up, but the usual monitor displays are visible, VitaGuard® is being supplied by batteries (four non-rechargeable batteries or the rechargeable block battery).

The light from the LED with the battery symbol is permanently on when the block battery is being charged in VitaGuard®. A depleted block battery takes up to six hours to recharge.

When the block battery is fully charged the LED with the battery symbol flashes every second to indicate that compensation charging is active. The block battery must therefore be fully charged at all times in the event that the power supply from the external power adapter fails.

## 4.5 The display

Each of the “Alarms, displays, and views during monitoring” are explained on page 69. Pressing the ◁ key in VIEW 1 takes you to the INFO screen with the current information for the doctor. Pressing it again takes you to the SYSTEM menu for the basic VitaGuard® settings.

**After the monitor is switched on it can take up to twenty seconds before the first values are displayed.**

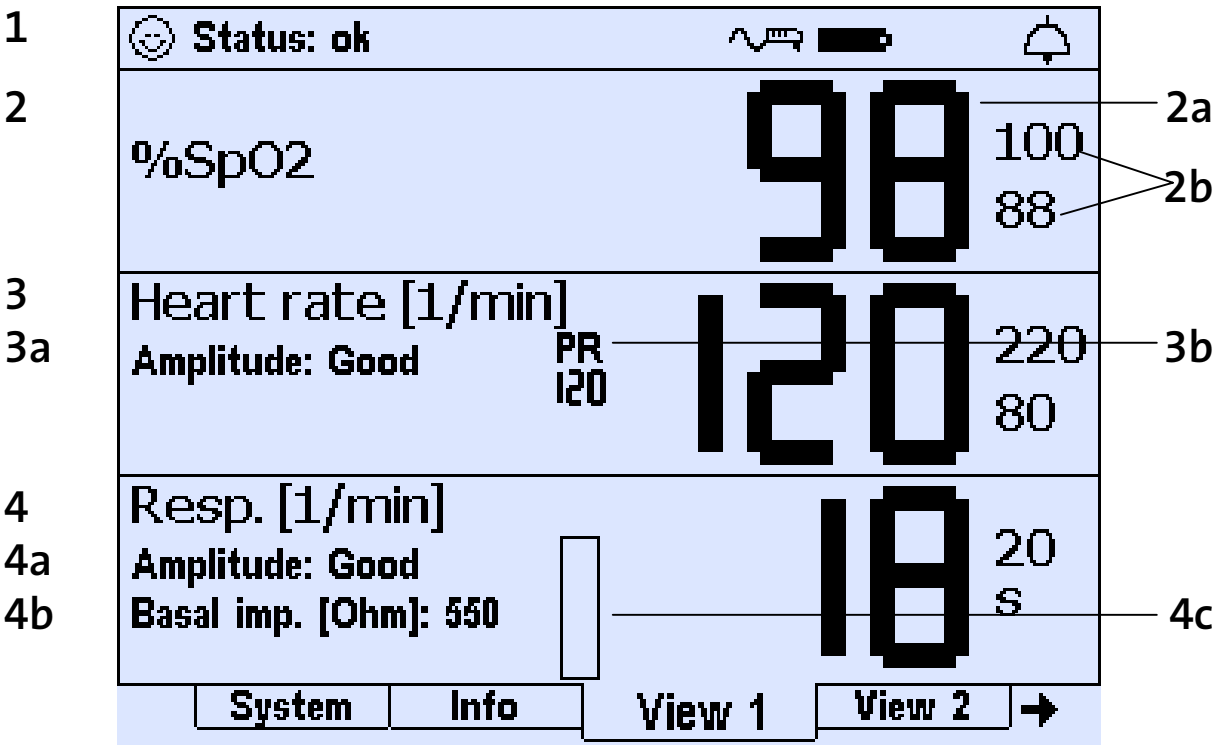
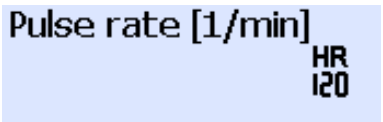



*Fig. 25 Current values and alarm limits in View 1*

1 The status line at the top of the display shows messages (on the left) and symbols (on the right) for the external power supply and alarm activation.

2 For all vital functions, as here $SpO_2$ **[2]**, the current value for each vital function **[2a]** is shown in large digits. Smaller digits to the right show the set alarm limits **[2b]**.

3 In addition to the The HEART RATE **[3]**, the quality of the signal amplitude **[3a]** is shown on the left. PULSE RATE will be displayed instead of HEART RATE **[3]** and PR **[3b]** instead of HR if the pulse oximeter is selected as the source for the heart rate alarms (rather than the ECG electrodes). The SYSTEM menu lets you deactivate the simultaneous display of PR or HR **[3b]**.




4 RESPIRATION **[4]** shows in addition on the left the quality of the amplitude **[4a]** and the basal impedance in ohms **[4b]**. This term is explained in the section “Checking the BASAL IMPEDANCE” on page 67. A respiration bar **[4c]** moves up and down synchroneously with the patient’s breathing.

# 5 Steps before and after monitoring

The following summary shows you all the necessary measures that need to be taken before monitoring. Also read information on how VitaGuard® is switched on and off.

**The doctor and the qualified medical staff are responsible for all other important activities when "Preparing for a new patient" (see page 99).**

## 5.1 Summary of steps before monitoring

- Insert the battery or batteries (do not switch on yet!).
- Use the external power adapter to connect VitaGuard® to the supply network (do not switch on yet!).
- Attach the $SpO_2$ sensor to the patient.
- Connect the $SpO_2$ patient cable to VitaGuard®.
- Connect the $SpO_2$ sensor to the patient cable.
- Connect the ECG patient cable to VitaGuard®.
- Attach the ECG electrodes to the patient.
- Connect the ECG electrodes to the patient cable.
- Switch on VitaGuard® as explained in the next section.
- Make sure that after the monitor is switched on the indicator lamps light up briefly and a short sound is emitted by the alarm buzzers.
- Check that the alarm limits displayed are the same as those recommended by the doctor.

## 5.2 Switching on

Press the <Enter> key for several seconds to switch on VitaGuard®.

**In the first minute of operation no acoustic signals are emitted so that you have time to check all cables. The alarm bell is crossed out for this time and the remaining time is shown next to it. Text messages, on the other hand, are shown from the beginning.**

When no patient cable is connected, an acoustic reminder signal is emitted as a short tone every twenty seconds after the monitor is switched on. The technical alarms for cable and electrode monitoring are not activated until the patient cable is connected and the first plausible data have been calculated. A text message in the status line reports from the beginning that the cables are being checked.

**After the device has been switched on, the following displays and signals show you that the monitoring system is fully operable.**

- All indicator LEDs light up briefly. During this time the alarm LED first lights up red and then yellow.
- A brief tone is emitted to indicate that the acoustic alarm buzzer is fully operable.

**If the alarm buzzer does not emit the acoustic signal after the device has been switched on, you must immediately send VitaGuard® to getemed AG or your authorized dealer for inspection. Please consult your authorized dealer for a replacement device.**

**Observe the patient carefully until the replacement device arrives. Bear in mind that the patient is not being monitored at this time and that no alarm will be reported in an emergency.**

## 5.3 Switching off

**Always switch off VitaGuard® in the manner described here.**

1 Press the <Enter> key and keep this pressed: the message PRESS Esc KEY appears.

2 Briefly press the <Esc> key, still keeping the <Enter> key pressed, and then release both keys.

The switch off command is acknowledged by two short beeps.

Data must be stored before the device finally switches off. For this reason, VitaGuard® needs about another two seconds after the keys are released until it switches off completely.

## 5.4 Summary of steps after monitoring

- Switch off VitaGuard® as explained in the previous section.
- Carefully detach the ECG electrodes from the patient.
- Disconnect the ECG electrodes from the patient cable.
- Detach the $SpO_2$ sensor, carefully removing the adhesive strip from the skin.

**If the procedure concerning stored data has not been clarified during your training, then please contact your doctor.**

# 6 Preparing for $SpO_2$ monitoring

**The information in this section refers primarily to the use of adhesive strip sensors. Also available, however, are $SpO_2$ sensors that can be disinfected and reused (permanent sensors) for brief examinations and for monitoring patients with allergies.**

- LNOP® Neo will be explained as an example $SpO_2$ sensor for children.
- LNOP® Adt will be explained as an example $SpO_2$ sensor for adults.

Preparing for $SpO_2$ monitoring involves:

- attaching the sensors to the patient
- laying and securing the patient cable
- connecting the $SpO_2$ patient cable to VitaGuard®

## 6.1 Safety instructions for $SpO_2$ monitoring

**For hygiene reasons, check that there is no damage to the sensor's packaging before opening it. Use adhesive strip sensors on the one patient only.**

**Remove the adhesive sensors no later than every eight hours and permanent sensors no later than every four hours so that you can inspect and, if necessary, clean the attachment sites on the patient's skin.**

**When the blood flow or attachment site is not satisfactory, attach the sensor to a different site, and inspect this site more often.**

**Be particularly careful with patients exhibiting weak blood flow: failing to check the sensors frequently may lead to skin damage and pressure-induced necrosis. Check no later than every two hours in these cases.**

**Connect the $SpO_2$ sensors only to the corresponding patient cable and this only to the corresponding socket on VitaGuard®.**

**Do not use adhesive strip $SpO_2$ sensors on patients exhibiting allergic reactions to adhesive strips or similar.**

**Securing sensors incorrectly, e.g. too tightly, can damage tissue.**

**Do not use damaged sensors. Replace sensors immediately if they exhibit any damage.**

**Do not immerse the sensors in liquids and do not attempt to sterilize them.**

**An improperly attached sensor can falsify measurements.**

**Do not attach the $SpO_2$ sensor to a limb that has or will have a catheter or pressure cuff during monitoring.**

**Secure the sensors and cables so that they cannot harm, strangle, or be swallowed by the patient. Always lay the patient cable at a safe distance from the patient's head and neck. Lay the patient cable when monitoring small children inside their clothing so that it exits at the foot. On larger children and adults you can, for example, lay the patient cable so that it exits between the trousers and pullover.**

**To prevent damage, avoid all kinks, folds, and any other unnecessary bends in the sensor cable.**

## 6.2 Operation of $SpO_2$ sensors

$SpO_2$ sensors consist of a transmitter diode (referred to as "transmitter" in the following) and a receiver. The transmitter is identified by the red star symbol on the adhesive strip. The receiver is identified by its round window and the white plastic part on the adhesive strip behind it.

The transmitter emits light, the receiver detects this light. When this light penetrates arterial blood vessels, the composition and intensity of the light picked up by the receiver change.

The $SpO_2$ monitor can calculate the percentage level of blood oxygenation from the composition of the light picked up by the receiver. However, it is important that no other light, whether daylight or ambient light, can reach the receiver. More detailed explanations can be found in the section “Measuring principle for the $SpO_2$ monitor” on page 135.

## 6.3 $SpO_2$ sensor adapted to the patient’s size and weight

The following lists a number of $SpO_2$ sensors that are also available.

- The LNOP® Neo delivered with VitaGuard® is an adhesive strip sensor for measuring the functional arterial blood oxygen saturation ($SpO_2$) of infants weighing up to 10 kg.
- Sensors of the type LNOP® NeoPt are available for monitoring premature infants with sensitive skin.
- The sensor LNOP® Pdt can be used on children weighing between 10 and 50 kg.
- The sensor LNOP® Adt is suitable for patients over 30 kg.

Information on other sensors can be obtained from getemed AG or your authorized dealer.

## 6.4 Choosing the sensor site

- Always choose a site that is intact, has good blood flow, and covers completely the receiver window. Information on choosing the right attachment site can be found on the sensor’s packaging.
- Choose a site such that the sensor’s transmitter and receiver can lie exactly opposite each other.
- The distance between the transmitter and the receiver should not be greater than two centimeters.

- On infants with thick or swollen feet, the big toe is often better than the whole foot.
- Clean and dry the attachment site.
- Choose a site where the sensor and patient cable can least restrict the patient's freedom of movement.

## 6.5 Repositioning or replacing the sensor

**Sensors used for a long time do not adhere as well as new ones.**

When VitaGuard® does not display plausible values for the pulse rate and oxygen saturation, the sensor may not be attached to the optimal site or may not be properly secured.

- Check the sensor's position, and if necessary, move the sensor to a different site.
- Always replace a sensor when the displayed pulse rate and the displayed percentage level of oxygen saturation remain unconvincing despite the sensor's new site.

## 6.6 Reasons for unconvincing $SpO_2$ values

**Clarify with the doctor whether one of the following situations may have arisen:**

- the sensor is improperly secured or used (e.g. when the transmitter and receiver do not lie exactly opposite each other),
- the patient moves vigorously,
- the sensor picks up bright ambient light, e.g. from powerful lamps, IR heater lamps, direct sunlight, etc.,
- venous pulsation,
- a catheter or pressure cuff has been applied to the same limb as the sensor,

- the blood exhibits appreciable quantities of dysfunctional hemoglobin, e.g. carboxyhemoglobin or methemoglobin,
- blood dyes have been used such as indocyanine green, methylene blue, or other substances that contain coloring agents and therefore affect the blood color.

## 6.7 Why the pulse rate is not displayed

**Clarify with the doctor whether one of the following situations may have arisen:**

- The sensor is secured too tightly (dangerous for the patient),
- Bright ambient light,
- Inflated blood pressure cuff on the same limb as the sensor,
- Arterial occlusion near the sensor,
- Low blood pressure, serious vasoconstriction, anemia, hypothermia, cardiac arrest, or shock.

## 6.8 Attaching the $SpO_2$ sensor to an infant's foot

**Note that the $SpO_2$ sensor type LNOP® Neo for infants is described here as an example. The doctor must decide which $SpO_2$ sensor type to use in each case.**

LNOP® Neo is an $SpO_2$ sensor for use with one patient only weighing less than 10 kg.

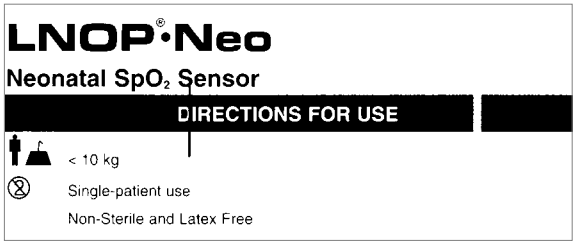



*Fig. 26 Label on the LNOP® Neo $SpO_2$ sensor*

LNOP® Neo is free of latex, is not sterile, and cannot be sterilized.

The foot is the preferred attachment site on newborns. Alternative sites are also the palms and backs of the hands.

On infants weighing between 3 and 10 kg with thick or swollen feet, the LNOP® Neo sensor can be secured to the big toe. In this case, the following information for the sensor's receiver does not refer to the sole of the foot, but to the underside of the big toe. An alternative attachment site is also the thumb.

1 Open the packaging and remove the sensor. Hold the sensor at the stem of the Y and remove the protective cover from both the sensor and the adhesive strip. Align the end of the sensor so that the contacts point away from the patient. Align the receiver along the fourth toe and press it against the sole of the foot (Fig. 27).

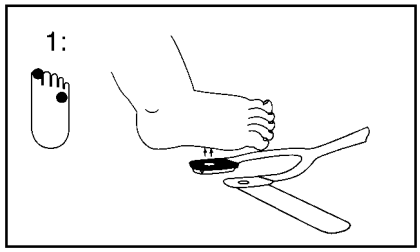



*Fig. 27 Positioning the sensor*

2 Align the transmitter window along the top of the foot directly opposite the receiver. Wrap the adhesive strip around the foot to secure the transmitter and receiver (Fig. 28). Check and if necessary correct the positions.

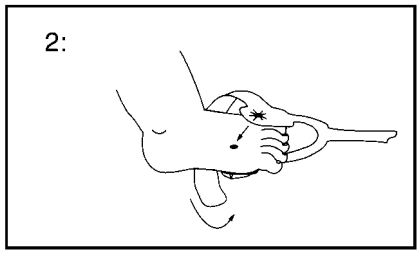



*Fig. 28 Aligning the sensor and receiver*

3 The opening in the receiver window must be completely covered by the foot (Fig. 29).

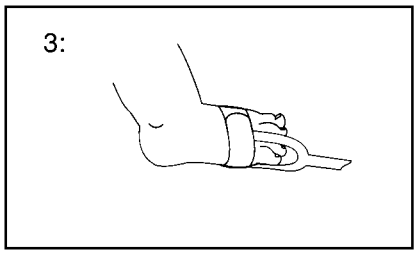



*Fig. 29 Correctly attached LNOP® Neo sensor*

## 6.9 Attaching the $SpO_2$ sensor to an adult's finger

**Note that the $SpO_2$ sensor type LNOP® Adt for adults is described here as an example. The doctor must decide which $SpO_2$ sensor type to use in each case.**

The LNOP® Adt sensor designed for adults weighing over 30 kg is identified by the label illustrated on the right.

*Fig. 30 Label on the LNOP® Adt $SpO_2$ sensor*

The preferred attachment sites on adults are the ring and middle fingers of the non-dominant hand. Alternative attachment sites are the other fingers of the non-dominant hand. On immobilized patients or patients whose hands cannot be used as attachment sites, the big or middle toe can be used.

1 Open the packaging and remove the sensor. Hold the sensor with the printed beige side downwards and bend it back to draw off the rear side. Align the sensor so that the receiver can be attached first (Fig. 31).

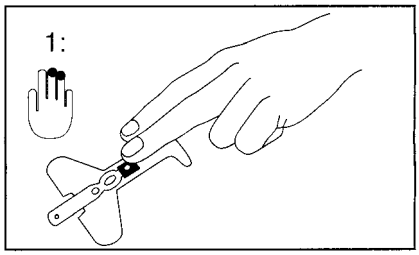



*Fig. 31 Positioning the sensor*

2 Now press the receiver on the fingertip and wrap the adhesive T ends around the finger (Fig. 32).

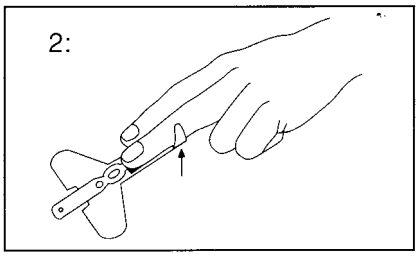



*Fig. 32 Positioning the receiver on the fingertip*

3 Next wrap the sensor with the transmitter and the finger design around the fingernail, and wrap the flaps downwards, one after the other, around the finger (Fig. 33).

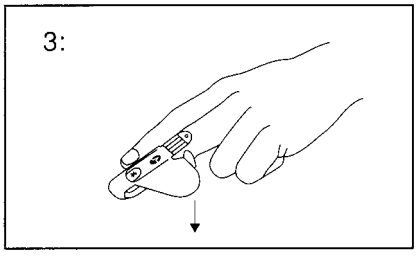



*Fig. 33 Aligning the sensor and receiver*

4 When the transmitter and receiver are correctly attached, they should be exactly opposite each other (Fig. 34). Check and if necessary correct the sensor's position. The receiver window must be completely covered by the tissue.

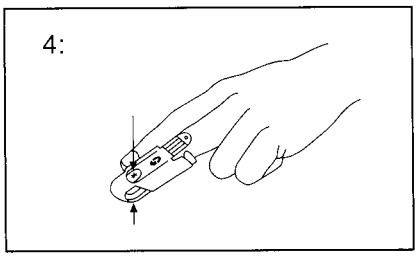



*Fig. 34 Correctly attached LNOP® Adt sensor*

## 6.10 Connecting the $SpO_2$ sensor and patient cable

Hold the sensor's contact blade so that the metal contacts are on the top and the two Masimo symbols on the blade and patient cable are opposite each other. Insert the contact blade into the patient cable until it engages (Fig. 35). Pull carefully on the contact blade to check that it has engaged properly. You can now secure the patient cable to the patient with an adhesive strip.

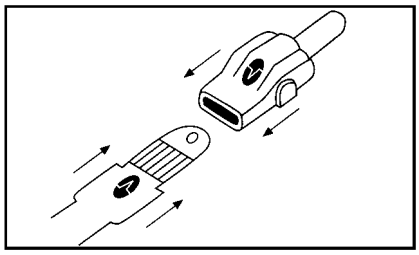


*Fig. 35 Connecting the patient cable and sensor contact*

## 6.11 Connecting the $SpO_2$ patient cable to VitaGuard®

Insert the patient cable's monitor plug into the $SpO_2$ socket on VitaGuard®. The Masimo inscription on the monitor plug must be on top. You should feel the monitor plug engage.

*Fig. 36 $SpO_2$ socket*

## 6.12 Disconnecting the $SpO_2$ sensor from the patient cable

Use the thumb and index finger of one hand to carefully press the two buttons on the side of the patient cable's socket (Fig. 37). Carefully pull the end of the sensor to withdraw it.

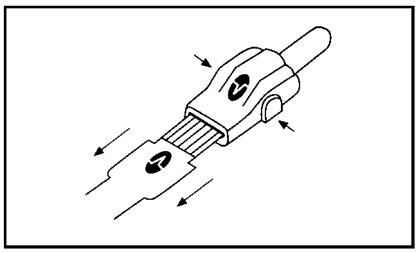


*Fig. 37 Disconnecting the sensor from the patient cable*

## 6.13 Disconnecting the $SpO_2$ patient cable from VitaGuard®

Using your thumb and index finger, carefully press the two levers in the patient cable's monitor plug, and carefully pull out the plug.

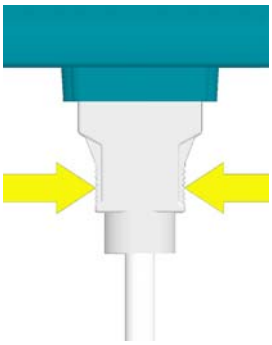


*Fig. 38 Two levers for securing and releasing the patient cable plug*

## 6.14 Reusing and refastening $SpO_2$ sensors

When the $SpO_2$ sensors are treated with care they can be used several times on the same patient as long as the adhesive surfaces still adhere and the transmitter and receiver windows are cleaned at regular intervals.

**Disconnect the sensor from the patient cable before you reattach or refresh it.**

- There are replacement adhesive strips available for the LNOP® Neo sensor used on infants.

- When sensors have been in use for a short time only, you can refresh the adhesive surfaces with a cotton swab saturated with a 70% isopropanol solution. Leave the sensor to dry thoroughly in air before reattaching it.
- A sensor can be secured with an adhesive strip on less sensitive patients. Velcro strips are available for more sensitive patients.

**Use a new sensor when the old one can no longer be properly secured.**

# 7 Preparing for heart rate and apnea monitoring

This section is divided into the following parts.

- Safety information when monitoring heart rate and apnea
- Connecting electrodes, the patient cable, and VitaGuard®
- Technical alarm from the electrode contact monitor
- Determining the optimal electrode configuration
- ECG lead, electrode color coding
- Optimizing the heart and respiration signals – signal amplitudes in VIEW 1
- Checking the BASAL IMPEDANCE

## 7.1 Safety information when monitoring heart rate and apnea

Observe the following points before monitoring with VitaGuard®.

**CAUTION Interference signals can prevent a heart rate alarm from being reported when under certain unfavorable conditions the monitor misinterprets these interference signals as heart signals. Interference signals can originate from the power supply or electrical apparatus in the monitor's environment. Observe the instructions under "Electromagnetic interference" on page 26.**

**The doctor can deactivate the APNEA ALARMS as described in the section "Settings in the RESPIRATION MENU (Settings PROTECTION OFF)" on page 129. The APNEA ALARMS are then no longer activated and OFF is displayed instead of the respiration rate. When a new age**

group is selected under ADMIT NEW PATIENT, the APNEA ALARMS are reactivated together with the other factory settings.

Use only those electrodes that getemed AG or an authorized dealer has delivered or approved. Other electrodes can, in particular when monitoring apnea, cause malfunctions and in addition cause damage to the patient's skin. Read and observe the operating instructions for the electrodes.

Do not continue using damaged electrodes or cables. Do not immerse electrodes or cables in water, solvents, or liquid cleaning agents.

Store the electrodes in a cool dry place. Observe the storage instructions on the packaging.

Do not use electrodes after their expiration dates (this date is printed on the packaging, e.g. FEB2006 or 2006-02 = February 2006).

The electrodes provided are designed for short-term applications. Using the same electrodes several times can lead to malfunctions when the adhesive surface fails to adhere properly.

Do not open the electrode's packaging until shortly before the electrode is to be used. Open the packaging and remove the electrodes. Hold the sides of the electrode and peel off the transparent film. Do not pull on the electrode's cable. Avoid finger contact with the electrode's gel-coated surface as much as possible.

If you intend to reuse the same electrode a short time later, carefully reattach them to the transparent film. This helps to prevent the electrode from drying out or becoming soiled.

Use exclusively the ECG patient cable delivered by getemed AG. Connect the ECG electrodes only to the ECG patient cable and this only to the corresponding VitaGuard® socket.

CAUTION Make sure when attaching electrodes that neither the electrodes nor their plug connectors come into contact with other electrically conducting parts. There must also be no contact with

other electrically conducting parts when electrodes become detached during monitoring.

Attach the electrodes only to intact areas of skin.

Secure the electrodes and cables so that they cannot harm, strangle, or be swallowed by the patient. Always lay the patient cable at a safe distance from the patient's head and neck. Lay the patient cable when monitoring small children inside their clothing so that it exits at the foot. On larger children and adults you can, for example, lay the patient cable so that it exits between the trousers and pullover.

Place the gel-coated side of the electrode on the chosen site and carefully press it several times for a good contact.

New electrodes may be reattached several times. Peel them gently from the skin starting at the edge.

When disconnecting the electrodes from the patient cable, do not pull on the electrode's cable. Pull the plug only.

If necessary, secure the cable with an adhesive strip. The skin should be dry and free of oil and grease.

Make sure when attaching and securing the patient cable that it cannot kink. Kinking can cause damage.

Do not pull on the cable: this is unpleasant for the patient and in addition can damage the electrodes.

## 7.2 Connecting electrodes, the patient cable, and VitaGuard®

Insert the electrode's plug into the ECG patient cable's distributor. Note the color coding of the electrodes and the distributor's sockets.

*Fig. 39 Color-coded sockets on the ECG patient cable's distributor*

Insert the plug from the ECG patient cable into the socket marked with the heart and lungs symbol.

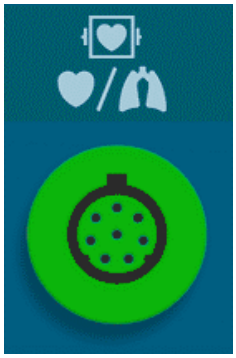


*Fig. 40 Electrode socket*

## 7.3 Technical alarm from the electrode contact monitor

The electrode contact monitor reports an alarm when:

- the electrodes have become detached,
- the electrodes are too dry (e.g. the expiration date has been exceeded or the electrodes have been used several times), giving rise to too high a value of basal impedance.

**When electrodes have become detached or when the electrical resistance between the electrode and skin is too high, the respiration and ECG signals are displayed as a zero line.**

When new electrodes have become detached you can reattach these by pressing them gently.

**You must replace electrodes that have become detached more than once or that exhibit too high a resistance between the electrode and skin. Further explanations can be found in the section “Checking the BASAL IMPEDANCE” on page 67.**

## 7.4 Determining the optimal electrode configuration

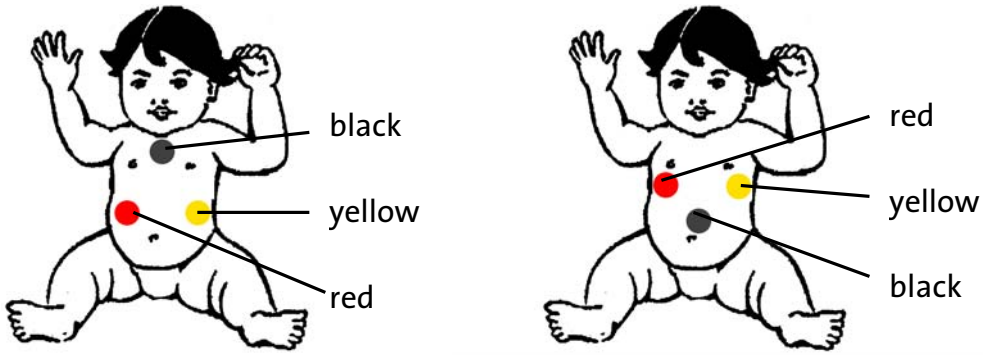
**The respiration and heart signals are detected using the same electrodes. The optimal electrode configuration involves finding good signal amplitudes for both the respiration and the heart signals simultaneously.**

getemed AG recommends that the responsible doctor determine the optimal electrode configuration. In most cases this configuration can be retained for the whole period of monitoring.

### 7.4.1 ECG lead, electrode color coding

Start with the electrode configuration depicted in Fig. 41 (see next page). First arrange

- the electrodes on infants as depicted in Fig. 41 a)
  (this electrode configuration has often proved successful because the abdominal wall of infants clearly moves synchronously with the respiration),
- the electrodes on all other patients as depicted in Fig. 41 b)




a) or b)

*Fig. 41 Recommended electrode configuration*

If the electrode configuration depicted in Fig. 41 does not yield a good signal quality, you can also try the alternative electrode configuration depicted in Fig. 42.

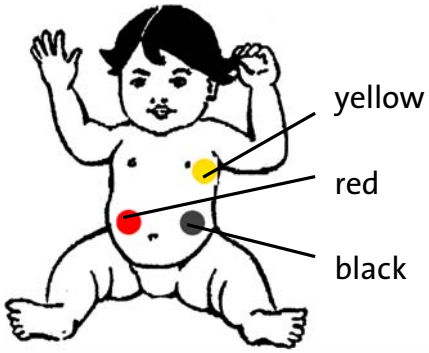



*Fig. 42 Alternative electrode configuration for optimizing the heart and respiration signals*

## 7.4.2 Optimizing the heart and respiration signals – signal amplitudes in VIEW 1

The amplitudes of the heart and respiration signals are displayed under the headings HEART RATE and RESPIRATION respectively in VIEW 1.

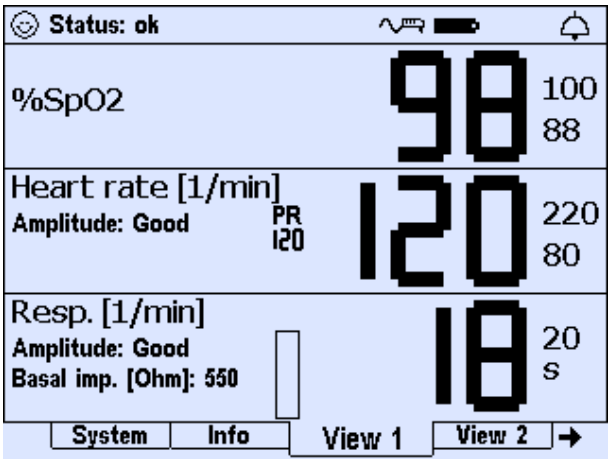
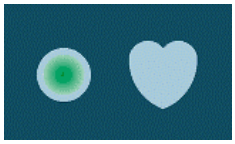


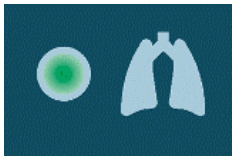

*Fig. 43 Electrode signal amplitude in View 1*

**CAUTION When AMPLITUDE: POOR is displayed, the values for the monitored heart rate and apnea may be imprecise.**

| Amplitude | Meaning |
|---|---|
| POOR | the signal is not or only sporadically detected |
| MEDIUM | the signal is detected, but interference, e.g. due to movement, can cause false alarms |
| GOOD | a clear signal is detected |



A correct HEART RATE is detected when the heart LED flashes synchronously with the patient's heartbeat. When the signal amplitude is GOOD or MEDIUM, there should be no deterioration in the detected heart rate when the patient moves normally.



Observe the LED with the lungs symbol and the respiration bar on the VitaGuard® display. Carefully change the positions of the red and yellow electrodes. Whenever possible, try to obtain the largest possible deflections in the respiration bar. Also, the respiration bar must move and the LED flash synchronously with the respiration.

## 7.5 Checking the BASAL IMPEDANCE

The basal impedance is displayed in View 1, the respiration display, and the display INFO\MEASUREMENTS: HR & RESP. The basal impedance is the sum of all impedances in the measuring circuit:

- skin and tissue impedance between the red and the yellow electrode
- impedance of the electrode-skin interface
- impedance of the electrodes themselves and the patient cable

The basal impedance slowly falls for the first few hours after the electrodes have been attached. This is caused by a reduction in the impedance at the electrode-skin interface.

The displayed basal impedance should be less than 1000 Ω. If not, wait for about fifteen minutes. When the basal impedance has still not fallen, you should use new electrodes.

When the displayed basal impedance does not lie within the specified range or when false alarms frequently occur, the doctor or the medical caregivers should observe the instructions in the section “Changing the ECG lead for signal optimization” on page 127.

# 8 Alarms, displays, and views during monitoring

**Immediately call the emergency services when a patient remains unconscious after being shaken or addressed.**

## 8.1 Alarm test

**CAUTION: When beginning monitoring at a new site, make sure that you can clearly hear the alarm signal and quickly reach the patient. For this purpose, deliberately trigger a technical alarm.**

When a patient is connected there are two ways you can deliberately trigger an alarm:

1 pull the red electrode plug out of the distributor on the ECG patient cable

or

2 disconnect the $SpO_2$ sensor from the $SpO_2$ patient cable.

## 8.2 HEART RATE values based on age groups

**Bear in mind that the HEART, PULSE, and RESPIRATION RATES drop considerably with increasing age. The doctor must check and, if necessary, adapt the alarm limits for each patient's age group.**

The percentage level of arterial blood oxygenation displayed as $\%SpO_2$ normally ranges between 97 and 99%, irrespectively of the patient's age group.

The average heart rate of an infant is much higher than that of an adult. Accordingly, the alarm limit e.g. for bradycardia (too low a heart rate) must be set considerably higher for an infant than for an adult patient. As an orientation aid, the following table lists some medically

acknowledged approximate heart rates for various age groups and stress situations.

| Age group | Heart rate / min | | |
|---|---|---|---|
| | Sleep | Rest | Stress (e.g. fever) |
| Newborns | 80–160 | 100–180 | max 220 |
| 1 week to 3 months | 80–200 | 100–220 | max 220 |
| 3 months to 2 years | 70–120 | 80–150 | max 200 |
| 2 to 10 years | 60–90 | 70–110 | max 200 |
| 10 years and older | 50–90 | 55–90 | max 200 |

## 8.3 Alarm message priorities in the status line

*Fig. 44 Status line on the VitaGuard® display*

Physiological alarms have high priority. The text messages of physiological alarms end with three exclamation marks.

!!!

Technical alarms have medium priority. The text messages of technical alarms end with two exclamation marks.

!!

## 8.4 Physiological and technical alarms

VitaGuard® generates two types of alarms: physiological and technical alarms.

- A **physiological alarm** is generated when VitaGuard® detects values that violate one or more of the set alarm limits for longer than the set period.

There are simple alarm limits, e.g. the LOWER LIMIT for the HEART RATE, and there are alarm limits based on the interaction of several monitor settings, e.g. the deviation alarms.

“Combining apnea alarms with heart rate and $SpO_2$ alarms” is explained on page 130.

- A **technical alarm** is generated when monitoring is no longer reliable, e.g. when electrodes have become loose.

The reasons for incorrect values can be detached electrodes or other technical defects. When a technical alarm condition occurs, a life-threatening situation may escape detection.

When, for example, a technical alarm condition relevant to $SpO_2$ has occurred, yet at the same time a physiological alarm condition has been detected by the heart rate and apnea monitor, the physiological alarm condition has priority and the physiological alarm is reported.

When, on the other hand, a technical alarm condition has been detected by the heart rate and apnea monitor and at the same time the $SpO_2$ monitor detects a physiological alarm condition, again the physiological alarm condition takes priority.

**NOTE An alarm mute time of ten seconds follows a technical alarm triggered by problems with the ECG electrodes or the $SpO_2$ sensor. This delay is to prevent false alarms when the physiological parameters are being recalculated. During the alarm mute time, the bell symbol in the status line is crossed out.**

## 8.5 Differentiating physiological and technical alarm signals

The ALARM TONE PITCH can be set in the SYSTEM menu so that alarms are heard over the prevailing background noise.

The urgency or priority of an acoustic alarm can be recognized by its characteristics described in the following.

High-priority messages emit two sequences of five tones that are repeated every ten seconds.

The interval between each tone packet is two seconds. Also, there is a slightly longer interval between the third and fourth tone of each sequence.

*Fig. 45 Characteristics of the high-priority acoustic alarm signal*

Medium-priority messages emit a sequence of three tones which is repeated every 5.2 seconds.

## 8.6 Acoustic information signals

If wished, the alarm unit next to the display can produce a short acoustic signal to accompany each heartbeat or each breath.

### 8.6.1 Information signals from the alarm unit next to the display

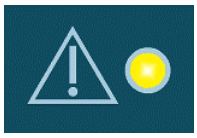
After the monitor is switched on, an acoustic reminder signal is emitted every twenty seconds until all sensors and electrodes are connected and plausible data have been detected.

### 8.6.2 Information signals from the sound aperture between the sockets

**A pulsating tone is emitted if the external power adapter is disconnected and no batteries are installed.**

## 8.7 The visual alarm signals

- A high-priority alarm, i. e. physiological alarm, causes the alarm LED to flash red.



- A medium-priority alarm, i. e. technical alarm, causes the alarm LED to flash yellow.

## 8.8 Status line displays

During monitoring the status line is displayed in all views.

*Fig. 46 The status line displayed in all views*

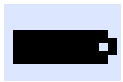
The monitor's text messages appearing on the left are explained in detail in the section "Alarm messages – meanings and other information" on page 77. On the right of the status line are three symbols.

- Power supply

The power supply symbol indicates whether the NA3000-2 external power adapter or the automobile power supply adapter is connected. When a power adapter is connected, the symbol appears as illustrated on the right. Otherwise the symbol is crossed out.

- Battery voltage indicator

The battery voltage indicator depicts the voltage from the batteries. When the block battery is being recharged this symbol is animated, i. e. a filling animation is displayed.



- Alarm indicator

When you interrupt an acoustic alarm by pressing the <Esc> key, the bell symbol is crossed out. To the left of the bell, the remaining alarm mute time is displayed in seconds. This mute time applies only to the current alarm type.

**When a new alarm condition is detected, the acoustic alarm is emitted before the alarm mute time has expired.**

Pressing the <Esc> key a second time immediately ends the ALARM MUTE TIME.

The alarm bell outline indicates that all acoustic alarm signals are enabled.

In the event of an alarm, the alarm bell is filled out and flashes.

## 8.9 $SpO_2$ monitor alarms

After the monitor has been switched on, it can take up to twenty seconds before the first values are displayed.

### 8.9.1 Physiological $SpO_2$ alarms

The currently set alarm limits are always displayed. When the displayed $SpO_2$ value falls below the $SpO_2$ LOWER LIMIT for longer than the period set under HYPOXIA ALARM DELAY or exceeds the $SpO_2$ UPPER LIMIT for longer than the period set under HYPEROXIA ALARM DELAY, an acoustic alarm signal is emitted and the corresponding message is displayed. The affected alarm limit and the alarm LED flash.

Go immediately to the patient when an alarm occurs and check the patient's condition.

When the $SpO_2$ value returns within the permitted range the alarm is ended automatically. In this case, the affected alarm limit and the alarm LED continue to flash until the <Esc> key is pressed to indicate that an alarm has occurred.

**The $SpO_2$ UPPER LIMIT is deactivated when it is set to 100% (factory setting). We recommend setting an upper limit when the patient is undergoing oxygen therapy.**

In addition to the alarms based on permanently set limits, deviation alarms can also be activated as explained in the section “Combining apnea alarms with heart rate and $SpO_2$ alarms” on page 130.

### 8.9.2 Technical $SpO_2$ alarms

The section “Table of technical alarm messages” on page 81 can be consulted for the technical alarm signals and the recommended troubleshooting procedures.

The $SpO_2$ monitor displays technical alarms with the corresponding messages. Until the problem has been eliminated, the $SpO_2$ value and the pulse rate are replaced by a question mark symbol. Perfusion and signal IQ are set to zero.

## 8.10 Heart rate and apnea monitoring

After the monitor is switched on, it may take up to twenty seconds before the first values are displayed.

### 8.10.1 Differentiating between heart and pulse rate

In the menu $SpO_2$, submenu $SpO_2$ MONITOR, the doctor can set the source for monitoring the heart rate when activating the $SpO_2$ module.

| Menu setting | $SpO_2$ monitor | Source for monitoring heart rate |
|---|---|---|
| OFF | switched off | ECG signal (heart rate) |
| ON (HR:ECG) | switched on | ECG signal (heart rate) |
| ON (PR:Masimo) | switched on | $SpO_2$ sensor (pulse rate) |

- When the ECG signal is set as the source for monitoring the heart rate, HEART RATE appears as the heading in various views. In addition – when this option has been activated – VIEWS 1 and 2 simultaneously display the current pulse rate determined via the $SpO_2$ sensor below the abbreviation PR.

- When the $SpO_2$ sensor is set as the source for monitoring the heart rate, the word PULSE RATE appears as the heading in various views. In addition – when this option has been activated – VIEWS 1 and 2 display the current heart rate determined via the ECG electrodes below the abbreviation HR.

**We recommend using the PULSE RATE for monitoring the heart rate only when the electrodes cannot be used, e.g. owing to allergic reactions.**

The heart and pulse rates can differ when irregular heartbeats fail to pump enough blood that can be recognized as a pulse.

## 8.10.2 Heart and pulse rate alarms

The currently set alarm limits are always displayed.

When the displayed HEART or PULSE RATE [HR or PR]

- falls below the LOWER LIMIT for longer than the set BRADYCARDIA DELAY or
- exceeds the UPPER LIMIT for longer than the set TACHYCARDIA DELAY
- or when the ECG signal is not detected for longer than the set ASYSTOLE DELAY

VitaGuard® emits an acoustic alarm signal and displays the corresponding message. The violated alarm limit and the alarm LED flash.

Go immediately to the patient when an alarm is reported and check the patient's condition.

The alarm is ended automatically when the heart rate returns within the permitted limits.

Deviation alarms can also be activated in addition to the alarms based on permanently set limits.

### 8.10.3 Apnea alarms

An alarm is reported when apnea, i.e. respiratory arrest, is detected for longer than the set APNEA DELAY. An alarm message then appears on the display, the alarm LED flashes, and an acoustic warning is emitted.

Go immediately to the patient when an alarm occurs and check the patient's condition. When the patient resumes breathing, the alarm is switched off automatically. Both the delay time and the alarm LED continue to flash to show that apnea has occurred for longer than the set APNEA DELAY. Pressing the <Esc> key stops the flashing.

### 8.10.4 Technical heart rate and apnea alarms

The section "Table of technical alarm messages" on page 81 can be consulted for the technical alarm signals and the recommended troubleshooting procedure. The heart rate and apnea monitors display technical alarms with the corresponding messages. Until the problem has been eliminated, the heart and respiration rates are replaced by a question mark symbol.

**When VitaGuard® is to be used as a pulse oximeter only, the absence of an ECG patient cable would normally generate a technical alarm. To prevent this technical alarm, the doctor can deactivate the apnea monitor and switch to PULSE RATE instead of HEART RATE as the source for heart related alarms.**

## 8.11 Alarm messages – meanings and other information

The tables in this section list in alphabetical order all the text messages that can appear on the VitaGuard® display together with more detailed explanations and troubleshooting hints.

## 8.11.1 Order of equal-priority alarm conditions

The numbers in the No. column on the right indicate the internal priorities that VitaGuard® uses to process the respective messages. This is of importance to the doctor only.

## 8.11.2 Table of physiological alarm messages

Physiological alarms are reported with high priority.

| Message | Meaning | Information | No. |
|---|---|---|---|
| Apnea detected!!! | A respiration signal has not been detected for longer than the set APNEA DELAY. | When there is no apnea:<br>- The electrodes are badly placed, i.e. the signal is too small to be detected.<br>- Cardiogenic artifacts are superimposed on the respiration signal so that it is rejected.<br>- The monitor, cable, or electrode is defect.<br>- The set APNEA DELAY is too short. | 10 |
| Apnea and $SpO_2$!!! | An $SpO_2$ and apnea alarm have occurred simultaneously. | See messages and information for “Apnea detected” and “$SpO_2$ too low”. | 4 |
| ECG amplitude low!!! | The monitor could not detect the ECG signal for longer than the set ASYSTOLE DELAY. | When there is no asystole (cardiac arrest or delay):<br>- The electrodes are badly placed.<br>- The ECG signal is too small to be detected.<br>- The monitor, cable, or electrode is defect. | 5 |
| Heart rate and apnea!!! | A heart rate alarm and an apnea alarm have occurred simultaneously. | See the messages and information for “Heart rate too high/ too low” and "Apnea detected”. | 3 |
| Heart rate and $SpO_2$!!! | A heart rate alarm and an $SpO_2$ alarm have occurred simultaneously. | See the messages and information for “Heart rate too high/ too low” and “$SpO_2$ too low”. | 2 |

| Message | Meaning | Information | No. |
|---|---|---|---|
| Heart rate too high!!! | The calculated heart rate exceeds the set UPPER LIMIT for longer than the set TACHYCARDIA DELAY. | When there is no tachycardia:<br>- T wave peaks are interpreted as R waves so that the calculated heart rate is too high.<br>- The electrodes are badly placed.<br>- Artifacts caused by excessive movement trigger false alarms.<br>- 50 Hz or other sources of electromagnetic interference trigger false alarms: suspected interference sources must be removed<br>- The electrode has become detached.<br>- The monitor, cable, or electrode is defect.<br>- The set UPPER LIMIT is too low. | 7 |
| Heart rate too low!!! | The calculated heart rate falls below the set LOWER LIMIT for longer than the set BRADYCARDIA DELAY. | When there is no bradycardia:<br>- Heartbeats are not detected.<br>- The electrodes are badly positioned.<br>- Abnormal beats, e.g. extrasystoles, are not detected.<br>- The electrode has become detached.<br>- The monitor, cable, or electrode is defect.<br>- The set LOWER LIMIT is too high. | 6 |
| Heart rate drop detected!!! (when activated) | The current heart rate falls below the value based on the set AVERAGING INTERVAL by more than the percentage deviation value set under TREND DEVIATION (–). | When there is no heart rate drop:<br>- The heart rate and/ or the average heart rate is incorrectly calculated for the reasons given under “Heart rate too low” | 11 |
| Heart rate rise detected!!! (when activated) | A heart rate rise is detected in the same manner as a heart rate drop, but TREND DEVIATION (+) is used instead. | When there is no heart rate rise:<br>- The heart rate and/ or its average is incorrectly calculated for the reasons given under “Heart rate too high”. | 12 |

| Message | Meaning | Information | No. |
|---|---|---|---|
| Multiple alarms!!! | An $SpO_2$ alarm, a heart rate alarm, and an apnea alarm have occurred simultaneously. | See the messages and information for "Heart rate too high/ too low", "$SpO_2$ too low", and "Apnea detected". | 1 |
| Pulse rate and apnea!!! | A pulse rate alarm and an apnea alarm have occurred simultaneously. | See the messages and the information for "Pulse rate too high/ too low" and "Apnea detected". | 3 |
| Pulse rate and $SpO_2$!!! | A pulse rate alarm and an $SpO_2$ alarm have occurred simultaneously. | See the messages and information for "Pulse rate too high/ too low" and "$SpO_2$ too low". | 2 |
| Pulse rate too high!!! | The calculated pulse rate exceeds the set UPPER LIMIT for longer than the set TACHYCARDIA DELAY. | When there is no tachycardia:<br>- Strong artifacts caused by excessive movement trigger false alarms.<br>- The monitor, cable, or sensor is defect.<br>- The set UPPER LIMIT is too low. | 7 |
| Pulse rate too low!!! | The calculated pulse rate has fallen below the set LOWER LIMIT for longer than the set BRADYCARDIA DELAY. | When there is no bradycardia:<br>- No pulse is detected.<br>- There are abnormal beats.<br>- The monitor, cable, or sensor is defect.<br>- The set LOWER LIMIT is too high. | 6 |
| Pulse rate drop detected!!! (when activated) | The current pulse rate has fallen below the value based on the set AVERAGING INTERVAL by more than the percentage deviation value set under TREND DEVIATION (–). | When there is no pulse rate drop:<br>- The pulse rate and/ or the average pulse rate is incorrectly calculated for the reasons given under "Pulse rate too low". | 11 |
| Pulse rate rise detected!!! (when activated) | A pulse rate rise is detected in the same manner as a pulse rate drop, but TREND DEVIATION (+) is used instead. | When there is no pulse rate rise:<br>- The pulse rate and/or the average pulse rate is incorrectly calculated for the reasons given under "Pulse rate too high". | 12 |

| Message | Meaning | Information | No. |
|---|---|---|---|
| $SpO_2$ too high!!! | The calculated $SpO_2$ exceeds the set UPPER LIMIT for longer than the set HYPEROXIA ALARM DELAY. | When $SpO_2$ is not too high:<br>- The sensor is incorrectly attached, e.g. it is too loose or too tight, the transmitter and receiver are too far apart, or they are not exactly opposite each other.<br>- The sensor has become detached<br>- The blood flow is weak or obstructed e.g. by a pressure cuff.<br>- Strong artifacts caused by movements corrupt the signal.<br>- The monitor, cable, or sensor is defect.<br>- The set UPPER LIMIT is too low. | 9 |
| $SpO_2$ too low!!! | The calculated $SpO_2$ has fallen below the set LOWER LIMIT for longer than the set HYPOXIA ALARM DELAY. | See “$SpO_2$ too high!!!”. | 8 |
| $SpO_2$ drop detected!!! (when activated) | The currently measured $SpO_2$ has fallen below the value based on the set AVERAGING INTERVAL by more than the percentage deviation value set under TREND DEVIATION (–). | When there is no $SpO_2$ drop:<br>- The present $SpO_2$ or the value based on the set averaging interval is incorrect for the reasons given under “$SpO_2$ too high”. | 13 |

## 8.11.3 Table of technical alarm messages

| Message | Meaning | Cause or elimination | No. |
|---|---|---|---|
| Check ECG cable!! | The monitor discovers that the ECG cable is not connected. | - Check the ECG cable. | 22 |
| Check electrodes!! | The monitor discovers that one or more electrodes are not connected. | - Check the electrodes: If this message persists, use new electrodes or replace the ECG cable. | 23 |

| Message | Meaning | Cause or elimination | No. |
|---|---|---|---|
| Check power adapter!! | The measured voltage from the power adapter is less than 8 V or greater than 10 V. | - Check that the stipulated power adapter is being used.<br>- Check and, if necessary, replace the NA3000-2 power adapter. | 16 |
| Conflicting HR limits!! | The heart rate's LOWER LIMIT has been set higher than the UPPER LIMIT. | - Correct the heart rate limits. | 19 |
| Conflicting $SpO_2$ limits!! | The $SpO_2$ LOWER LIMIT has been set higher than the UPPER LIMIT. | - Correct the $SpO_2$ limits. | 20 |
| Corrupted ECG signal!! | The ECG signal is corrupted too strongly by 50 Hz interference signals from the supply network. | - Attach the electrodes as symmetrically as possible.<br>- Replace the electrodes.<br>- Select the "I YE-RD, 3" lead.<br>- Proceed in accordance with the section "Electromagnetic interference" on page 26. | 24 |
| Hardware fault!! | The monitor has detected an internal fault. | - Switch off the monitor, wait for thirty seconds, and switch it back on: if this message persists, the monitor is defect. | 14 |
| Internal data error!! | The internal software monitor has detected a data transfer error. | - Switch off the monitor, wait for thirty seconds, and switch it back on: if this message persists, the monitor is defect. | 18 |
| No cables connected!! | The monitor discovers that both patient cables are not connected. | - Connect the patient cables for $SpO_2$ and ECG. | 21 |
| No power adapter !! | The power adapter has been disconnected. | - Reconnect the external power adapter or press the <Esc> key. | 17 |
| Recharge battery!! | The battery voltage is too low: the monitor can no longer operate reliably | - Operate the monitor with the external power adapter to recharge the block battery, or insert non-rechargeable batteries. | 32 |
| Replace batteries!! | The battery voltage is too low: the monitor can no longer operate reliably. | - Insert new batteries or a new block battery or operate the monitor with the external power adapter. | 33 |

| Message | Meaning | Cause or elimination | No. |
|---|---|---|---|
| $SpO_2$: Check cable!! | The $SpO_2$ module reports that the $SpO_2$ cable is not connected. | - Connect the $SpO_2$ cable.<br>- Replace the $SpO_2$ cable, if this message persists. | 26 |
| $SpO_2$: Defective sensor!! | The $SpO_2$ module reports that the $SpO_2$ sensor is defect. | - Replace the $SpO_2$ sensor. | 27 |
| $SpO_2$: Hardware fault!! | The $SpO_2$ module is not supplying data. | - Switch off the monitor, wait for thirty seconds, and switch it back on: if this message persists, the monitor is defect. | 15 |
| $SpO_2$: Interference!! | The $SpO_2$ module detects electromagnetic interference. | - Locate any interference sources in the direct vicinity and, if necessary, remove them. | 30 |
| $SpO_2$: Pulse search!! | When switched on, at first, the $SpO_2$ module reports that it is searching for the pulse. | - When this message is displayed during monitoring, check whether the sensors are secured and positioned properly. | 34 |
| $SpO_2$: Sensor off!! | The $SpO_2$ sensor is defect or not connected. | - Check whether the $SpO_2$ sensor is correctly connected to the cable; if necessary replace the sensor. | 28 |
| $SpO_2$: Too much light!! | The $SpO_2$ module reports that there is too much light. | - Protect the $SpO_2$ sensor from light sources, e.g. by covering it. | 31 |
| $SpO_2$: Unrecognized sensor!! | The $SpO_2$ module reports that an unrecognized sensor is connected. | - Replace the $SpO_2$ sensor<br>(use only the sensors from Masimo Inc.). | 29 |

# 8.12 Table of information messages

| Message | Cause | Meaning | No. |
|---|---|---|---|
| Calculating heart rate | The current heart rate cannot be displayed while it is being calculated. | The current heart rate is displayed after it has been calculated. | 37 |
| Heart and pulse rates diverge!! | The heart rate determined via the ECG electrodes differs from the pulse rate by more than ±40%. | - Check the ECG electrodes and the $SpO_2$ sensor.<br>- See also the messages for “Heart rate too high”, “Heart rate too low”, “Pulse rate too high”, “Pulse rate too low”. | 38 |
| Internal battery too low | The internal battery for alarms during a power failure is depleted. | - The monitor is defect i. e. the internal battery needs to be replaced by a technician. | 39 |
| $SpO_2$: Low perfusion | The $SpO_2$ module reports that the blood flow is too weak. | - Either use a different attachment site, or set SENSITIVITY to MAXIMUM in the $SpO_2$ menu. | 35 |
| $SpO_2$: Low signal IQ | The $SpO_2$ module reports that the signal quality is low. | - Use a different attachment site, or check for the presence of light or electromagnetic interference sources in the vicinity.<br>- Whenever possible, prevent vigorous movements by the patient. | 36 |
| Status: ok | No messages | | 40 |

# 9 Alarm and monitor settings

**The functions described in this section can be accessed only when the doctor has set SETTINGS PROTECTION to LIMITED in the SYSTEM menu. This setting requires a code.**

**The function ADMIT NEW PATIENT in the SYSTEM menu overwrites all earlier settings.**

The set alarm limits and other monitor parameters are stored and retained when the monitor is switched back on after a battery change.

## 9.1 Safety instructions for the alarm settings

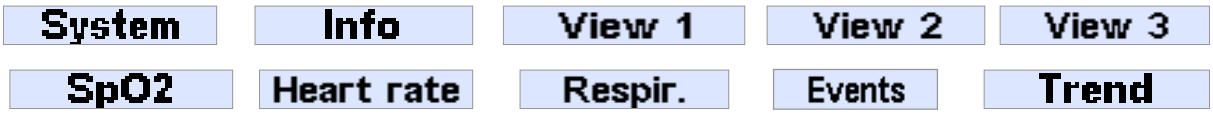
**It is important that the doctor responsible sets new alarm limits and monitor parameters for each patient and for each new medical situation. Never change alarm limits without consulting the treating doctor.**

**Never set the alarm limits to extreme values that render the monitoring system useless.**

**When you have been given a code for changing alarm limits, it is important that you treat this code as confidential. Life is in danger when alarm limits are not adapted specifically to each and every patient.**

## 9.2 Summary of views and menus

The views presented here are intended to provide extensive information on the monitoring situation. When SETTINGS PROTECTION is set to LIMITED, they can be accessed with the direction keys ◁ and ▷.




The keys △ and ▽ let you access more detailed information and enter menus for changing monitor settings.

- The △ or ▽ key takes you from the SYSTEM view to the SYSTEM menu. The first setting is highlighted.
- The △ or ▽ key leafs through pages on the INFO display.
- The △ or ▽ key takes you from VIEW 1, 2, or 3 to the menu "MANUAL DATA STORAGE or TRANSMIT DATA". This is explained in the corresponding section on page 116.
- The $SpO_2$, HEART RATE, and RESPIRATION displays each feature a menu for adjusting the respective settings and can be accessed with the △ or ▽ key. The first setting is highlighted.
- The △ or ▽ key takes you from the EVENTS or TRENDS views to detailed views, WAVEFORMS, and TRENDS.

## 9.3 Additional views

When the doctor has configured VitaGuard® so that also the caregivers can change settings, i.e. SETTINGS PROTECTION is set to LIMITED, VIEWS 2 and 3 are also activated in addition to VIEW 1. VIEW 1 is explained in the section "The display" on page 46.

### 9.3.1 View 2 – Large data presentation and waveforms

View 2 displays in large digits the current values for the monitored vital functions and, on the right in smaller digits, the set alarm limits.

Also, each section on the left presents a waveform of the monitored vital function.

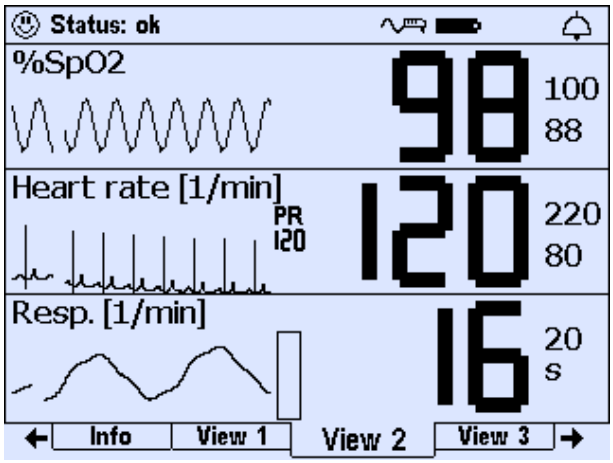



*Fig. 47 View 2*

### 9.3.2 View 3 – Smaller data presentation and waveforms

The top half of View 3 displays the current measured values and the alarm limits.

The bottom half of View 3 displays the waveforms over a longer interval than View 2.

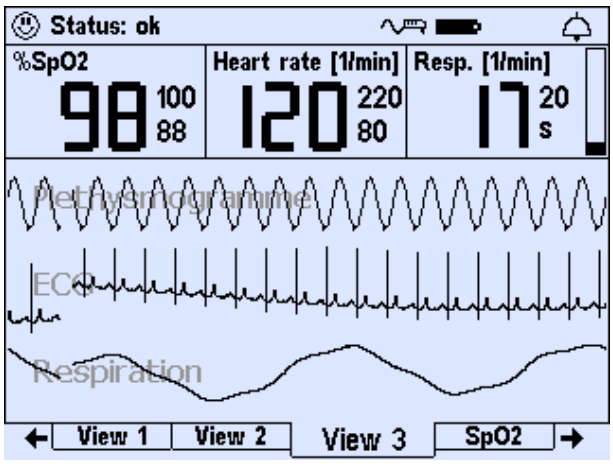



*Fig. 48 View 3*

## 9.4 Changing the settings

Use the direction keys to highlight a menu option or an entry in this option. Once you have highlighted the option you want, press the <Enter> key to change it. When you do not want to keep your changes, press the <Esc> key.

The △ key takes you to the menus. The first entry in the list is highlighted. Use the ▽ key to highlight the setting LCD BRIGHTNESS (“Changing multiple-component settings” is explained on page 109 for the doctor and qualified medical staff).

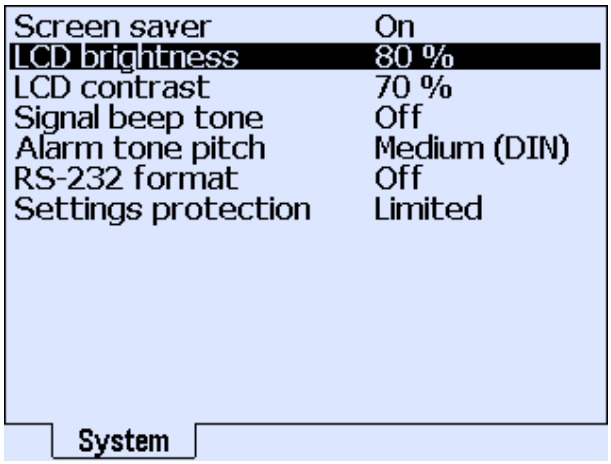



*Fig. 49 Menu system, “LCD brightness: 80%” highlighted*

Press the <Enter> key. A window appears where you can change the old value.

Use the △ and ▽ keys to change the highlighted value.

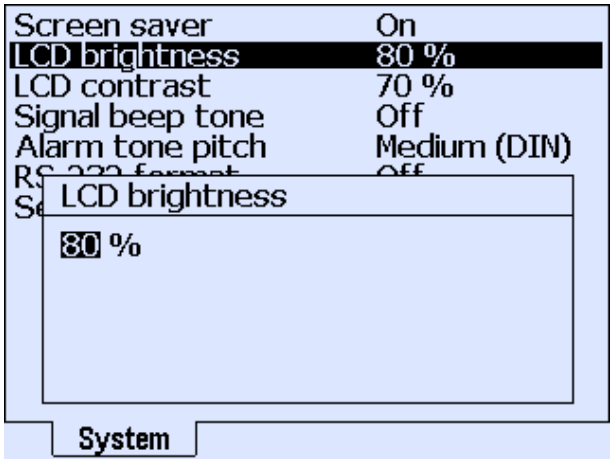



*Fig. 50 System, “LCD brightness” highlighted in the change window*

Pressing the <Enter> key after changing a value causes a prompt to appear with ACCEPT: No highlighted. Press the ◁ key to highlight ACCEPT: YES.

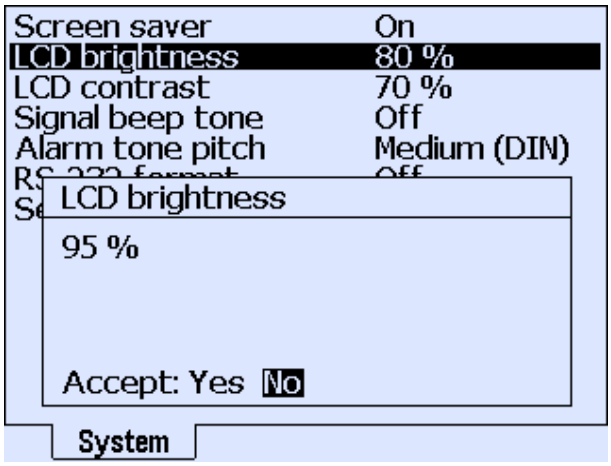



*Fig. 51 System, accept change to LCD brightness highlighted*

Confirming the prompt ACCEPT: YES with the <Enter> key displays the changed value in the list. To exit the menu press the <Esc> key.

## 9.5 SYSTEM menu – general settings

**NOTE You can familiarize yourself with the menus without changing values. Simply press the <Esc> key to exit each menu and submenu without saving changes.**

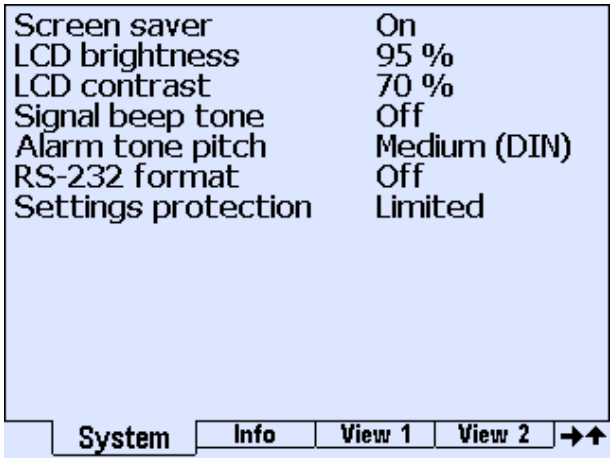



*Fig. 52 System menu – general settings*

### 9.5.1 SYSTEM\ SCREEN SAVER (OFF/ ON)

When SCREEN SAVER is set to ON, an animation appears on the display when no key has been pressed for five minutes.

When you press a key or an alarm is triggered, the previous mask is displayed again.

### 9.5.2 SYSTEM\ LCD BRIGHTNESS

You can set the LCD BRIGHTNESS from 0% to 100% in steps of 5%. When 0%, the display's backlight illumination is switched off. The factory setting is 95%.

### 9.5.3 SYSTEM\ LCD CONTRAST

You can set the display's contrast from 0% to 100% in steps of 5%. The factory setting is 70%.

### 9.5.4 System\ Signal beep tone

You can configure the monitor to emit a brief signal tone with every detected respiration (Respiration) or with every detected heartbeat (Heart/ pulse beat).

When this tone disturbs the patient or caregivers, choose the setting Off.

The factory setting is Off.

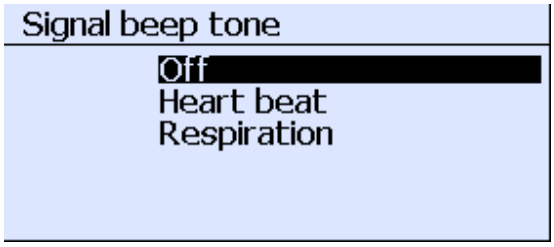



*Fig. 53 System\ submenu "Signal beep tone"*

### 9.5.5 System\ Alarm tone pitch

You can set the pitch of the acoustic alarm signals to Low, Medium, or High so that they can be heard over the expected background noise. The DIN settings (DIN) match the alarm tone characteristics as described from page 71 on in the section "Differentiating physiological and technical alarm signals". As an alternative, you can set the alarm tone characteristic (gtm) as familiar from other getemed devices.

The factory setting is Medium.

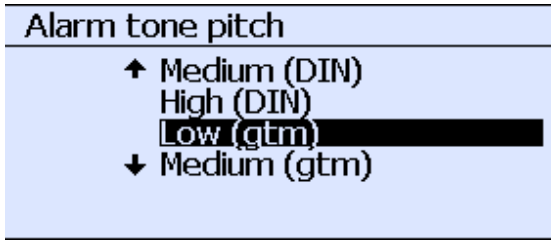



*Fig. 54 System\ submenu "Alarm tone pitch"*

### 9.5.6 System\ RS232 format

This submenu lets you assign the format for online data output from the AUX serial port.

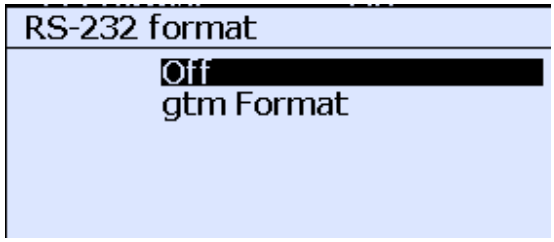



*Fig. 55 System\ RS232 format*

### 9.5.7 System\ Settings protection On, Limited, Off

**The codes that protect the alarm defaults from unauthorized changes must be given by the doctor to those persons only whom the doctor judges to be adequately informed about monitoring and their responsibility for the patient. The doctor should point out that the code must be treated as confidential, that settings should be changed at the doctor's request only, and that all changes must be confirmed by the doctor.**

VitaGuard® provides the following three settings for Settings protection.

- **Settings protection ON** deactivates all options to change monitor settings. The display presents only View 1, the Info display, and the System menu.
- **Settings protection Limited** enables access to all views and menus. Of all the monitor settings, however, only the alarm limits can be changed.
- **Settings protection Off** enables all views and menus and allows changes to all monitor settings.

**The factory setting is Settings protection Limited.**

After highlighting the function Settings protection, press the <Enter> key to open a submenu.

- This submenu always displays Settings protection as "00" irrespectively of the current setting. Pressing the <Enter> key activates Settings protection.
- When you enter a code Settings protection appears as Limited.
- When you enter a different code, Settings protection appears as Off.

**When the wrong code has been entered three times Settings protection cannot be so easily deactivated. In this case, consult your authorized dealer.**

# 9.6 $SpO_2$ display and menu

The ▷ key takes you from VIEW 1, 2, or 3 to the $SpO_2$ display. Here you can open the menu with the △ or ▽ key. Having highlighted a row, press the <Enter> key to change its contents.

## 9.6.1 $SpO_2$ view

The top half of the display presents:

1 the status line

2 the current value with the set alarm limits

3 the current three-minute trend views that update the last value every two seconds

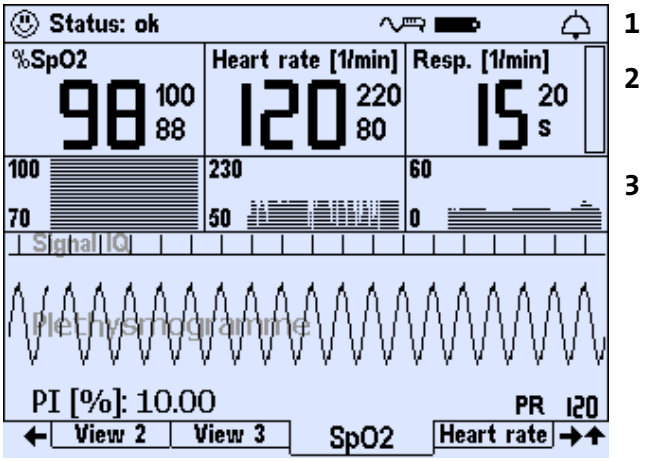



*Fig. 56 $SpO_2$ view, plethysmogram, perfusion index, and signal IQ*

The $SpO_2$ trend displays the $SpO_2$ values between 70 and 100% over the last three minutes.

The first row under the trend view is the SIGNAL IQ as vertical bars, the second the PLETHYSMOGRAMME. At the bottom perfusion index [PI] and pulse rate [PR] are displayed.

When the monitor is switched on, it can take up to twenty seconds before the first values are displayed.

**Bear in mind that the plethysmogram is NOT proportional to the pulse volume. A regular plethysmogram, for example, indicates that the $SpO_2$ sensor is correctly secured.**

Every time the $SpO_2$ monitor detects a pulse beat a vertical bar appears in the SIGNAL IQ row. The higher this bar, the better the signal from the $SpO_2$ sensor. A high SIGNAL IQ indicates that:

- the sensor is correctly attached,
- an adequately strong signal is detected for the arterial blood flow,
- the patient does not move or is not moved too vigorously.

The calculated percentage value for PERFUSION (PI) can vary between 0 and 20%. When this value is very low, $SpO_2$ and the pulse rate are no longer monitored. When the SENSITIVITY in the $SpO_2$ menu is set to MAXIMUM, the cut-off limit is 0.02%; when set to STANDARD, this limit ranges from 0.5 to 0.02%, depending on the signal quality.

The principal of operation for this calculation can be found in the section “Measuring principle for the $SpO_2$ monitor” on page 135.

### 9.6.2 $SpO_2$ menu – alarm settings (SETTINGS PROTECTION LIMITED)

The $SpO_2$ menu lets you view and change the current $SpO_2$ alarm settings.

Changes are permitted only when SETTINGS PROTECTION is set to LIMITED in the SYSTEM menu.

Factory settings are shown in bold type.

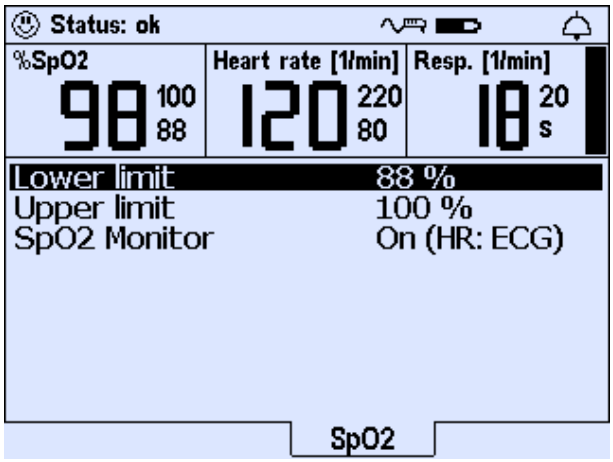



*Fig. 57 $SpO_2$ menu for viewing and setting alarm limits*

LOWER LIMIT ..... 50, 51 ... **88** ... 99, 100 %
Lower alarm limit for the measured arterial oxygen saturation; an alarm is reported when the measured value falls below this limit for longer than the set HYPOXIA ALARM DELAY

UPPER LIMIT ..... 50, 51 ... 88 ... 99, **100** %
Upper alarm limit for the measured arterial oxygen saturation; an alarm is reported when the measured value exceeds this limit for longer than the set HYPEROXIA ALARM DELAY

$SpO_2$ MONITOR ..... OFF/
**ON (HR: ECG) /**
ON (PR: MASIMO)
Here you can view or set the following: whether the $SpO_2$ monitor is deactivated or, when it is activated, whether the heart rate derived from the ECG electrode signals or the pulse rate derived from the $SpO_2$ sensor is used as the alarm criterion.

## 9.7 HEART RATE display and menu

**Depending on the setting in the $SpO_2$ menu, you can decide whether the heart rate derived from the ECG electrode signals or the pulse rate derived from the $SpO_2$ sensor is used as the alarm criterion.**

The ▷ key takes you from VIEW 1, 2, or 3 to the heart rate display. From here you can open the menu with the △ or ▽ key. When a row is highlighted, press <Enter> to change the corresponding value.

### 9.7.1 HEART RATE display

The top half of the display presents:

1 the status line

2 the current values with the set alarm limits

3 the current three-minute trends that update the last value every two seconds

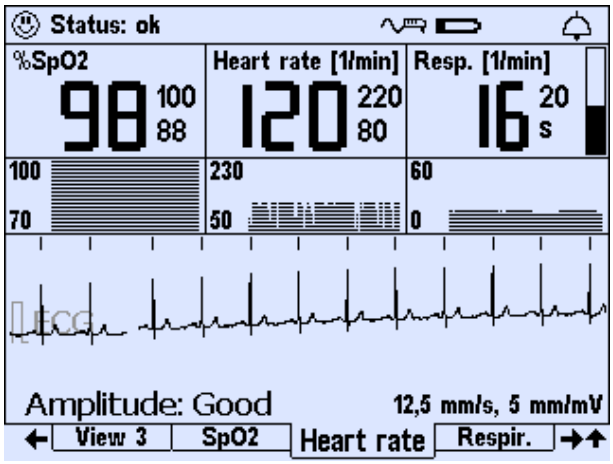



*Fig. 58 Heart rate display*

The heart rate trend display presents the heart rate over the last three minutes. This display varies with the set age group:

| | **0 TO 2 YEARS** | 2 TO 6 **YEARS** | >6 YEARS |
|---|---|---|---|
| HEART RATE TREND DISPLAY [PER MIN] | between 230 and 50 | between 180 and 50 | between 150 and 45 |

The bottom half of the display presents the ECG. A small vertical bar above the ECG indicates every detected heartbeat. Under the ECG you can see the evaluated amplitude of the ECG signal known from VIEW 1.

### 9.7.2 HEART RATE menu – alarm settings (SETTINGS PROTECTION LIMITED)

The HEART RATE menu lets you view and, if necessary, change the current heart rate settings. You may have to adapt the default age group alarm limits to the current patient. These settings can be changed only when SETTINGS PROTECTION has been set to LIMITED in the SYSTEM menu.

Different heart rate alarm limits can be set as the default values for each age group:

| Default | 0 to 2 years | 2 to 6 years | >6 years |
|---|---|---|---|
| Lower heart rate limit [/min] | 80 | 60 | 55 |
| Upper heart rate limit [/min] | 220 | 150 | 140 |

In the event of persistent false alarms, a different lead can be set in the Heart rate menu as explained in the section “Changing the ECG lead for signal optimization” on page 127.

The heart rate’s Lower limit can be set from 30 to 180 beats and the heart rate’s Upper limit from 100 to 255, each in steps of five beats per minute.

Factory settings are shown in bold type.

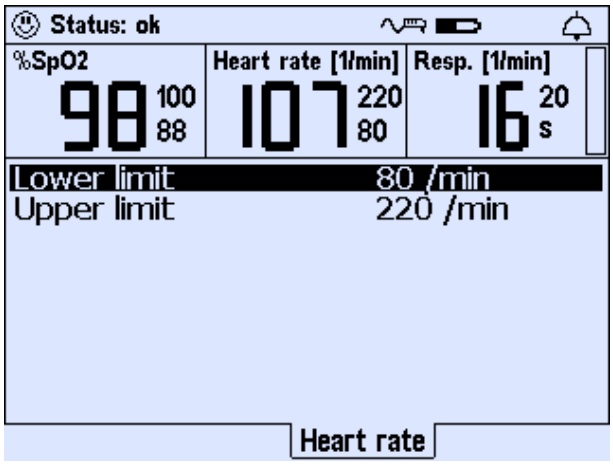



*Fig. 59 Heart rate menu for viewing and setting alarm limits*

Lower limit (heart rate) ..... 30, 35 ... **80** ... 175, 180/min
Lower limit for the heart rate; an alarm is reported when the heart rate falls below this limit for longer than the set Bradycardia delay

Upper limit (heart rate) ..... 100, 105 ... **220** ... 250, 255/min
Upper limit for the heart rate; an alarm is triggered when the heart rate exceeds this limit for longer than the set Tachycardia delay

## 9.8 Respiration display and menu

The ▷ key takes you from View 1, 2, or 3 to the Respiration display. From here you can open the menu with the △ or ▽ key. Having highlighted a row, press <Enter> to change the corresponding value.

### 9.8.1 RESPIRATION display

The top half of the display presents:

1 the status line

2 the current values with the set alarm limits

3 the current three-minute trends that update the last value every two seconds

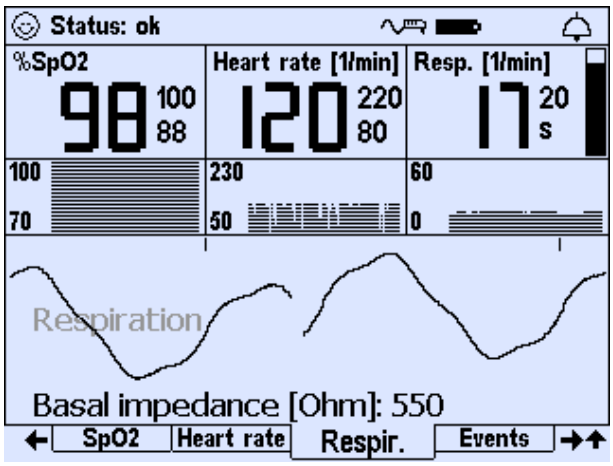



*Fig. 60 Respiration display, respiration graph*

The RESPIRATION trend display presents the respiration rate over the last three minutes. This display varies with the set age group:

| | **0 TO 2 YEARS** | 2 TO 6 **YEARS** | **>** 6 **YEARS** |
|---|---|---|---|
| RESPIRATION RATE TREND DISPLAY [PER MIN] | between 0 and 60 | between 0 and 60 | between 0 and 30 |

The bottom half of the RESPIRATION display presents the respiration waveform. A small vertical bar above the respiration waveform indicates every detected respiration signal. Under the respiration curve you can see the respiration signal's BASAL IMPEDANCE in ohms, as in VIEW 1.

**The displayed respiration rate is not used in the alarm assessment and is calculated and displayed only when the respiration signal exhibits an adequate amplitude and is relatively free of movement artefacts. Otherwise a question mark is displayed. This has no negative effects on either the alarm function or the detection of central apneas.**

### 9.8.2 Respiration menu – alarm settings (Settings protection Limited)

These settings can be changed only when Settings protection is set to Limited in the System menu.

Factory settings are shown in bold type.

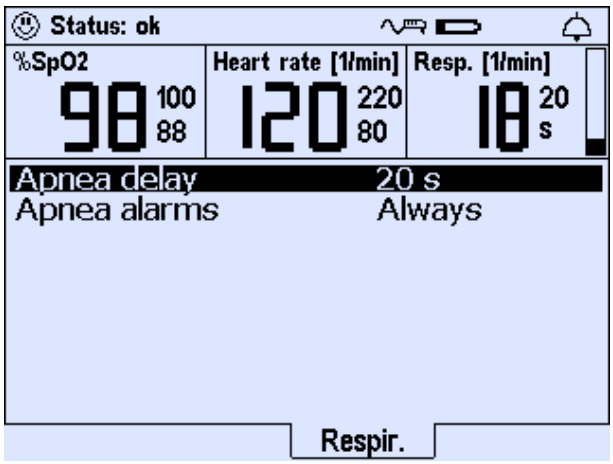



*Fig. 61 Respiration menu for viewing and setting alarm limits*

Apnea delay ..... 8, 10 ... **20** ... 32, 34 seconds
VitaGuard® interprets apnea and triggers an alarm when a respiration signal or movement is not detected and Apnea delay is exceeded. The doctor must have set Apnea alarms to Always.

Apnea alarms ..... Off/**Always**/Combined

**CAUTION A deactivated apnea monitor can no longer detect apnea!**

Off and **Always** switches off and on the apnea monitor. In both cases the respiration waveform is displayed and stored. When Apnea alarms is set to Combined, an apnea alarm is triggered only when at the same time an apnea is detected shortly before a change in Heart rate and/ or $SpO_2$ (see Section 10.14).

# 10 Information for the doctor and qualified medical staff

**The treating doctor is responsible for monitoring with VitaGuard®. This also applies to ambulatory monitoring.**

**This section contains all safety and settings information that only the treating doctor can make decisions on. Remember that all the information and instructions in the sections “Intended use” on page 14 and “Safety” on page 22 must also be observed.**

**Only getemed AG personnel or authorized dealers certified by getemed AG as medical product advisers in accordance with § 31 MPG (German Medical Products Act) may instruct the doctor and the qualified medical staff on how to handle and use VitaGuard®. This certification is awarded only to those persons that have received adequate training from getemed AG for its products.**

## 10.1 Safety instructions

The safety instructions in this section address special technical and medical issues that are of particular importance to the doctor and qualified medical staff.

### 10.1.1 Preparing for a new patient

**When more than one VitaGuard® monitor with differing settings are used in the same environment, there is a risk of mixing monitors and a particular patient may be monitored with unsuitable settings. For this reason check the currently set alarm limits every time the monitor is switched on.**

**It is important that VitaGuard® is configured so that false alarms are avoided to the greatest possible extent. Frequent false alarms can prove detrimental to the alertness of caregivers.**

**When VitaGuard® is to be used for a new patient, the doctor or the qualified medical staff are obliged to take the following important precautionary measures.**

- Place used consumables such as electrodes or sensors in a plastic bag before disposing of them in household or medical waste.
- Clean the device and disinfect all cables (e.g. as described in the guidelines from the Robert Koch Institute).
- Insert new batteries or a fully charged block battery.
- Select the age group in SYSTEM\ ADMIT NEW PATIENT as explained under “SYSTEM\ ADMIT NEW PATIENT – restoring factory settings” on page 110.
- Check that the monitor settings are suitable for the patient and, if necessary, adapt them.
- Consider that the monitor settings may need to be changed at a future date and, as appropriate, arrange appointments to change these settings.
- Check that the acoustic alarm signal is loud enough to be heard over the prevailing or expected noise levels in the monitor’s environment.
- When necessary, set SETTINGS PROTECTION to LIMITED.
- When necessary, train caregivers in the necessary resuscitation measures.

### 10.1.2 Connections to the USB and AUX ports

The USB port is designed to transfer data to a PC. The AUX port can interface with a modem for remote data transfer.

**Observe the standard DIN EN 60601-1-1 for connections to systems consisting of multiple medical devices and to systems consisting of medical and non-medical devices.**

**A device must comply with the regulations under DIN EN 60601-1 for medical devices or under DIN EN 60950 for communication technology devices before it is connected to the USB or AUX ports. In addition, the leakage current from the VitaGuard® must be measured as stipulated in the standard DIN EN 60601-1-1. This leakage current must not exceed 100 µA. Only qualified medical device technicians can check whether the leakage current conforms to the standards.**

**When several devices are connected to each other, the individual leakage currents can add up and may pose a risk to the patient.**

**Do not connect printers, cameras, scanners, or other devices.**

### 10.1.3 VitaGuard® and other medical devices

**When VitaGuard® is to operate at the same time as a defibrillator, the monitoring results may be invalid for a short time. In addition, defibrillation can damage the cables. Check the monitoring system after defibrillation.**

**Bear in mind that an external defibrillation pulse can be attenuated. A test in accordance with DIN EN 60601-2-49 showed that defibrillation pulses emitted during monitoring with electrodes and $SpO_2$ sensors are attenuated by less than 10 %.**

**Do not use VitaGuard® in conjunction with HF surgical equipment, TENS devices, or nerve stimulators.**

**VitaGuard® correctly interprets pacer pulses with amplitudes greater than 5 mV, so VitaGuard® can be used on patients with pace makers.**

**Warn your pacemaker patients that the displayed heart rate may possibly be affected by stimulating pulses. Point out to the caregivers that they must carefully observe pacemaker patients.**

**Do not operate VitaGuard® near MRI devices (magnetic resonance imaging) or other systems that generate strong electromagnetic fields. The electrode leads, for example, can heat up by induction, causing burns under the electrodes and fire in the cables. The strong magnetic fields generated by magnetic resonance image devices can cause permanent damage to VitaGuard®.**

### 10.1.4 Safety instructions for the doctor – $SpO_2$ monitor

**Regard the $SpO_2$ monitor as an early warning device. When the $SpO_2$ monitor tends towards too low blood oxygen saturation, blood samples should be analyzed to clarify the situation.**

**Intravascular coloring agents and the associated possible rise in carboxyhemoglobin (COHb) and methemoglobin (MetHb) levels can lead to imprecise $Sp0_2$ measurements.**

**An intra-aortic balloon pump can distort these values. For this reason, check the pulse rate against the ECG heart rate.**

**Circulatory centralization, i.e. when the organism contracts the vessels to reduce the flow of blood to the extremities, can suppress or otherwise distort the monitored $SpO_2$ values. Circulatory centralization can arise when e.g. patients are anesthetized, suffer from shock, or are under great physical strain. Ear sensors, for example, are available for short-term applications.**

**A pulse oximeter may not be used as an apnea monitor.**

## 10.2 INFO display

The INFO display quickly presents the doctor with a summary of the monitor settings and data. Other INFO windows can be accessed with the direction keys △ and ▽.

**The current page number and the total number of pages are displayed in the top right. For example, “1/10” means “the first of ten pages”.**

### 10.2.1 INFO\ LAST STATUS MESSAGES

The last status messages provide information on the directly preceding monitoring period. Here you can see when and why a message appeared.

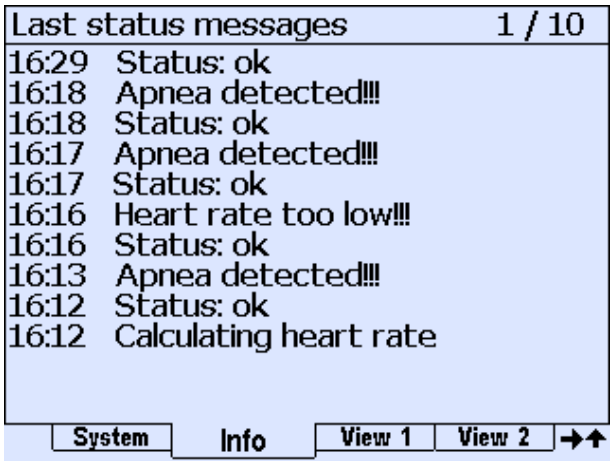



*Fig. 62 Info\ Last status messages*

### 10.2.2 INFO\ GENERAL

- INTERNAL BATTERY

This displays the state of the INTERNAL BATTERY permanently installed in VitaGuard®.

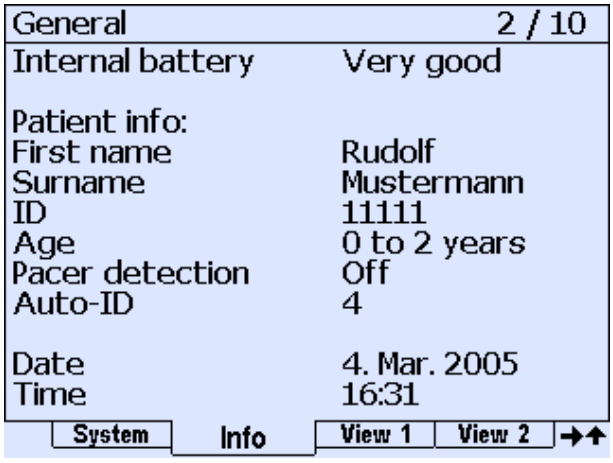



*Fig. 63 Info\ General*

- PATIENT NAME/ PATIENT ID

The patient's name and ID are displayed when VitaWin® has transferred these from a PC to VitaGuard® or when they have been keyed in as explained in the section "SYSTEM\ ADMIT NEW PATIENT – restoring factory settings" on page 110.

- AGE

This displays the age group that has been set as explained in the section "SYSTEM\ ADMIT NEW PATIENT – restoring factory settings" on page 110.

- PACER DETECTION

When the patient has a pacemaker, set PACER DETECTION in the HEART RATE menu to ON: this prevents the monitor from processing stimulating pacemaker pulses as R waves.

- AUTO-ID

This displays the ID number that is automatically assigned every time the ADMIT NEW PATIENT function is executed.

- DATE, TIME

This displays the date and time of the internal clock which can be set in the SYSTEM menu.

## 10.2.3 INFO\ MEASUREMENTS: $SpO_2$

INFO\ MEASUREMENTS: $SpO_2$ displays various average values for $SpO_2$ calculated since the monitor was switched on.

These values are lost when the monitor is switched off.

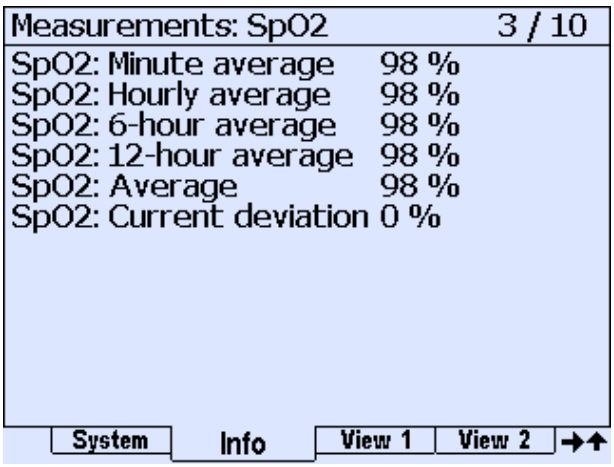



*Fig. 64 Info\ Measurements: $SpO_2$*

$SpO_2$: Average is calculated over the Averaging interval set in the $SpO_2$ menu. The Current deviation shows how much the current $SpO_2$ deviates from the Average in percent. This deviation is used for reporting deviation alarms when $SpO_2$ Alarms in the $SpO_2$ menu has been set to Limits & trends.

### 10.2.4 Info\ Measurements: Pulse rate

Info\ Measurements: Pulse rate displays the various average pulse rate values calculated since the monitor was switched on.

These values are lost when the monitor is switched off.

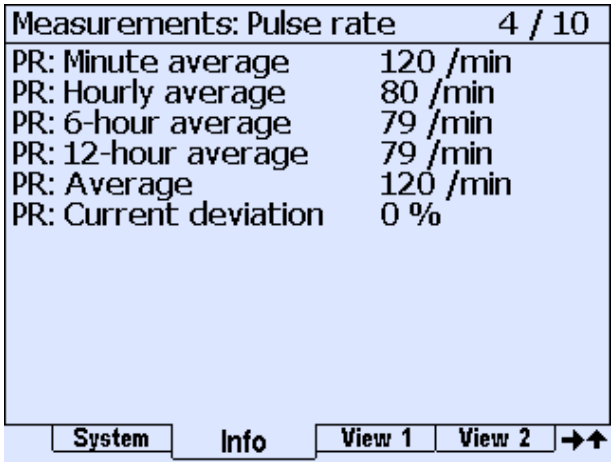



*Fig. 65 Info\ Measurements: Pulse rate*

PR: Average is calculated over the Averaging interval set in the Heart rate menu. The Current deviation shows how much the current pulse rate deviates from the Average in percent.

### 10.2.5 Info\ Measurements: HR & Resp.

Info\ Measurements: HR & resp. displays the various average heart rate values calculated since the monitor was switched on. These values are lost when the monitor is switched off.

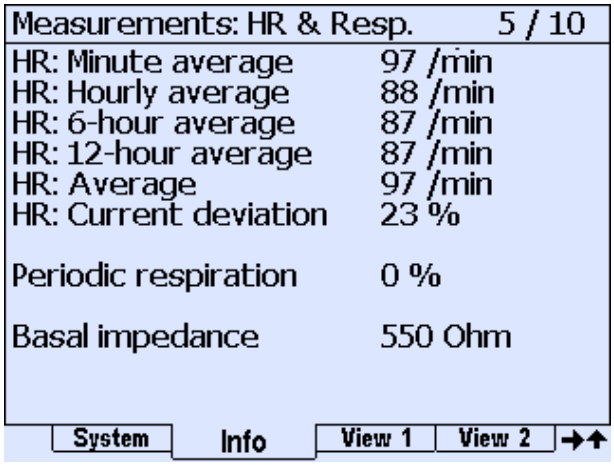



*Fig. 66 Info\ Measurements: HR & Resp.*

HR: AVERAGE is calculated over of the AVERAGING INTERVAL set in the HEART RATE menu.

HR: CURRENT DEVIATION shows how much the current heart rate deviates from the AVERAGE in percent.

This DEVIATION is used for triggering deviation alarms when HEART RATE ALARMS has been set to LIMITS & TRENDS in the HEART RATE menu and when ON(HR:ECG) (i.e. heart rate and not pulse rate) has been selected as the source for heart rate alarms under $SpO_2$\ $SpO_2$ MONITOR. This setting is restored as the factory setting when the ADMIT NEW PATIENT function is executed in the SYSTEM menu.

PERIODIC RESPIRATION displays the time in percent that PERIODIC RESPIRATION has been detected since the monitor was switched on. This value is displayed only when the function PERIODIC RESPIRATION is set to ON in the RESPIRATION menu and when AGE GROUP is set to 0 TO 2 YEARS under SYSTEM\ ADMIT NEW PATIENT.

BASAL IMPEDANCE displays the value measured between the yellow and the red electrode (see “Checking the BASAL IMPEDANCE” on page 67).

### 10.2.6 INFO\ SETTINGS: OXIMETER

This window presents all the settings for $SpO_2$ monitoring that are not shown in VIEWS 1 to 3.

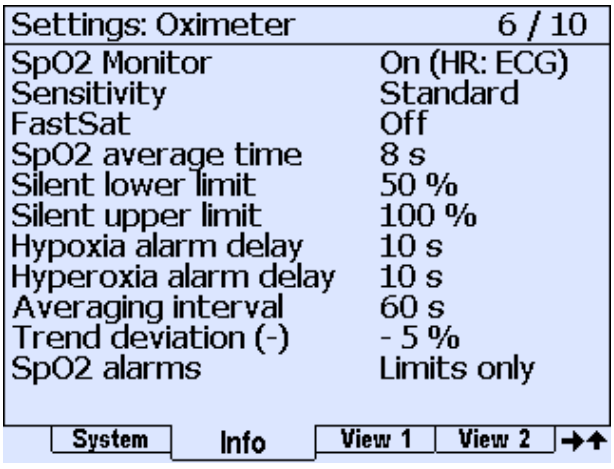



*Fig. 67 Info\ Settings: Oximeter*

### 10.2.7 Info\ Settings: Heart rate

This window presents all the settings for heart rate monitoring that are not shown in Views 1 to 3.

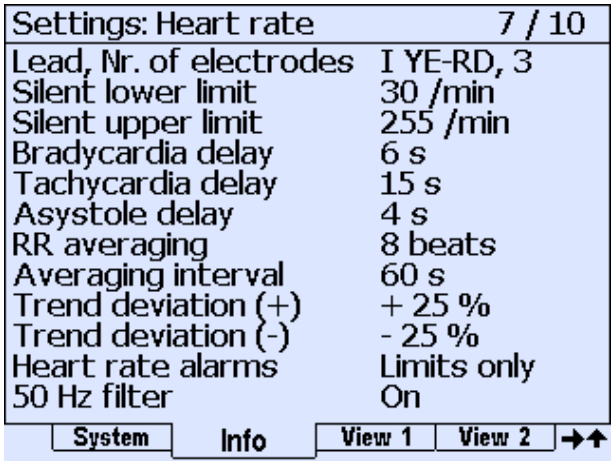

Settings: Heart rate 7 / 10
Lead, Nr. of electrodes I YE-RD, 3
Silent lower limit 30 /min
Silent upper limit 255 /min
Bradycardia delay 6 s
Tachycardia delay 15 s
Asystole delay 4 s
RR averaging 8 beats
Averaging interval 60 s
Trend deviation (+) + 25 %
Trend deviation (-) - 25 %
Heart rate alarms Limits only
50 Hz filter On
System
Info
View 1
View 2

*Fig. 68 Info\ Settings: Heart rate*

### 10.2.8 Info\ Settings: Apnea monitor

This window presents all the settings for apnea monitoring that are not shown in Views 1 to 3.

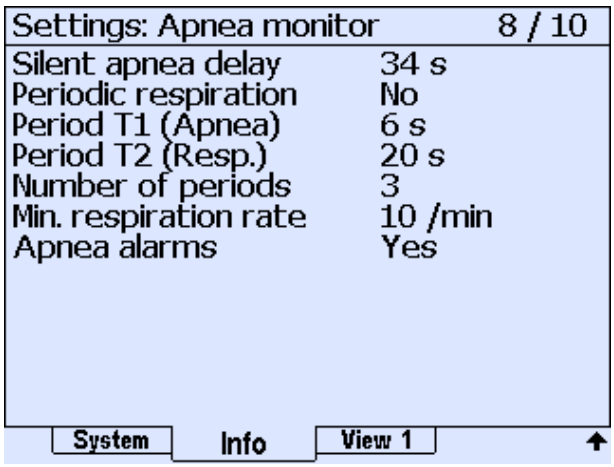



*Fig. 69 Info\ Settings: Apnea monitor*

### 10.2.9 Info\ Memory/ Internet

This displays the current Memory used and the total Memory size.

Also displayed is Telephone, i.e. the modem number that the monitor automatically dials for remote data transfer. This telephone number must be loaded by the evaluation software VitaWin® and cannot be edited directly in the monitor.

Here you can also view the details for transferring data as an e-mail attachment.

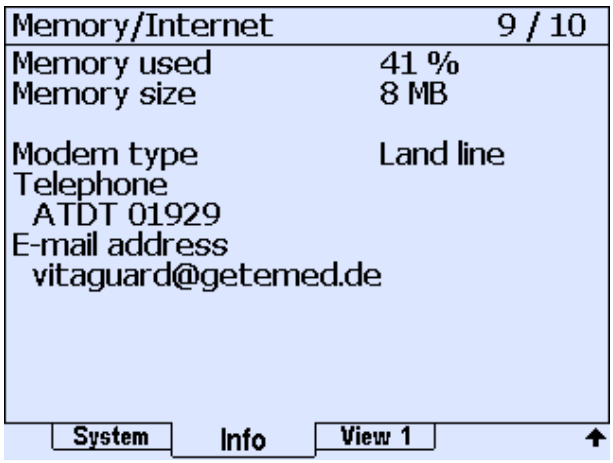



*Fig. 70 Info\ Memory*

## 10.2.10 Info\ Versions

Info\ Versions displays the software and hardware version numbers.

The software and hardware from Masimo for monitoring $SpO_2$ are also displayed, followed by the monitor's serial number (SN).

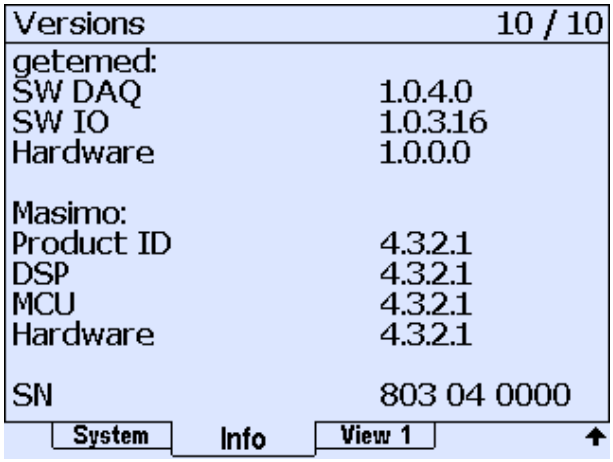



*Fig. 71 Info\ Versions*

## 10.3 Settings in the SYSTEM menu (SETTINGS PROTECTION OFF)

When SETTINGS PROTECTION is switched off in the SYSTEM menu, the doctor can configure VitaGuard® for specific monitoring requirements.

Use the direction keys to highlight an entry. When you want to change the entry, press the <Enter> key. Pressing the <Esc> key discards any changes without saving.

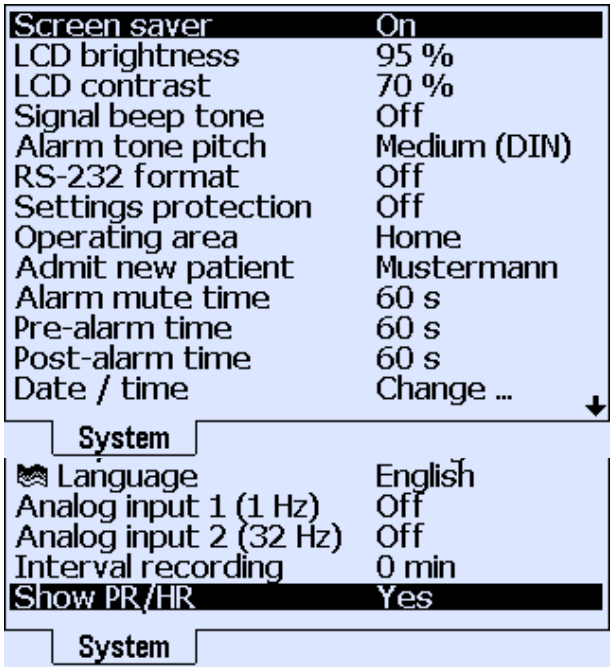



*Fig. 72 Separately protected settings in the System menu*

### 10.3.1 Changing multiple-component settings

The following example for changing the date and time in the SYSTEM menu is intended to explain how you can change system settings consisting of several components.

Use the ▽ key to highlight the entry DATE/ TIME.

Press <Enter>. A window appears for changing the old entry.

Use the keys ◁ and ▷ to highlight the component you want to change.

The highlighted value is changed with the keys △ and ▽.

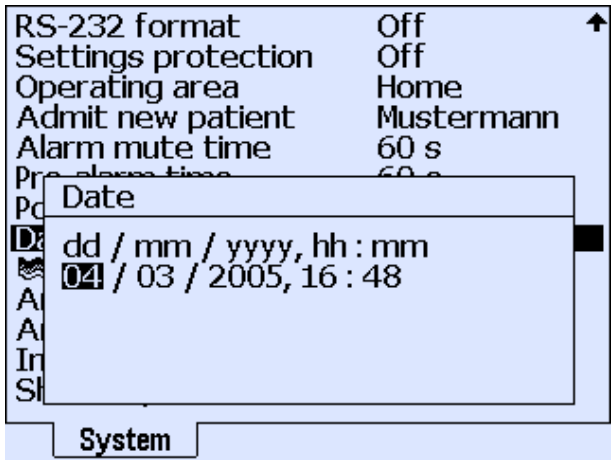

RS-232 format Off
Settings protection Off
Operating area Home
Admit new patient Mustermann
Alarm mute time 60 s
Date
dd / mm / yyyy, hh : mm
04 / 03 / 2005, 16 : 48
System

*Fig. 73 System\ Date/ time*

After changing a value, pressing the <Enter> key a second time causes a prompt to appear with ACCEPT: NO highlighted. Press the ◁ key to highlight ACCEPT: YES. Confirming the prompt ACCEPT: YES with the <Enter> key displays the changed value in the list. To exit the menu press the <Esc> key.

### 10.3.2 SYSTEM\OPERATING AREA: HOME or CLINIC

OPERATING AREA lets you decide whether the value you have entered for SETTINGS PROTECTION is retained the next time VitaGuard® is switched on.

When you select HOME, SETTINGS PROTECTION is ON when the device is next switched on.

When you select CLINIC, SETTINGS PROTECTION is set to the selected value when the device is next switched on.

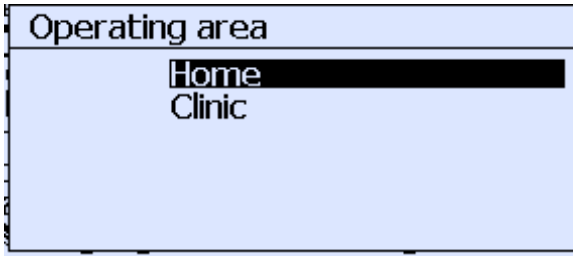



*Fig. 74 Operating area: Home or Clinic*

### 10.3.3 SYSTEM\ ADMIT NEW PATIENT – restoring factory settings

**IMPORTANT: This deletes all stored data and all monitor settings for a specific patient.**

**Check that the new monitor settings are suitable for the patient.**

All data are deleted and all user settings are restored to the factory values, so you are prompted whether you want to CONTINUE. Press the ◁ key to highlight ACCEPT: YES and then the <Enter> key.

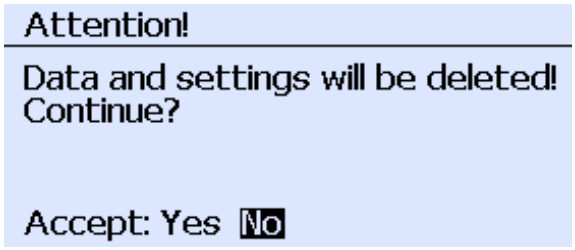



*Fig. 75 Warning before changes under System\ Admit new patient*

The submenus for ID, First name, and Surname are displayed one after the other.

Use the ◁ and ▷ keys to position the cursor.

Use the △ and ▽ keys to enter letters and numbers.

Press the <Enter> key after you have entered your data in each submenu.

These inputs are optional and can be skipped by pressing the <Enter> key.

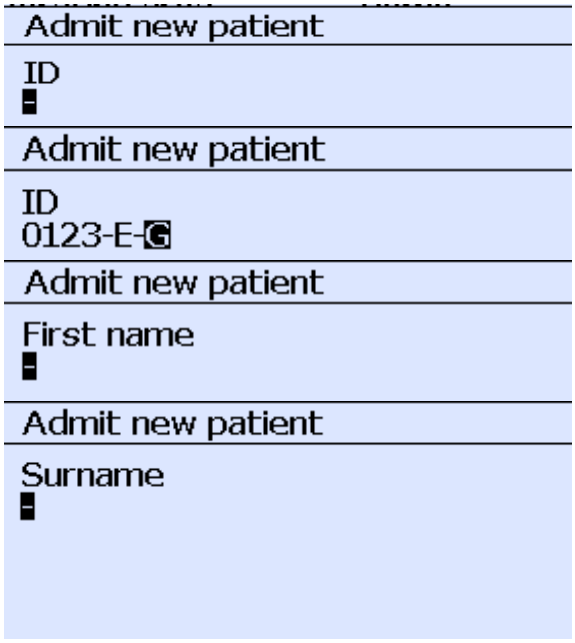



*Fig. 76 System\ ID, First name, and Surname*

Pressing the <Enter> key to confirm your entry in the Surname menu opens the submenu for setting the age group. Here too, press the <Enter> key to confirm your age group settings.

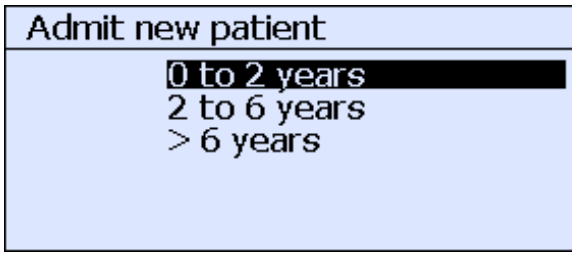



*Fig. 77 System\ Age group*

Use the ◁ key to highlight Accept: Yes and then press the <Enter> key, your settings for the new patient are stored.

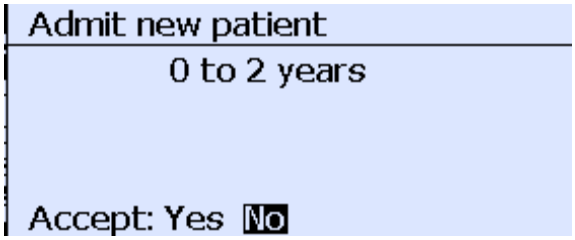



*Fig. 78 Confirming the age group setting*

**The Admit new patient function restores the factory settings.**

**VitaGuard® is delivered with alarm limits for patients in the 0 to 2 years age group.**

**The following settings vary with the age group:**

- the minimum Respiration rate in the Respiration menu

- the Lower limit and the Upper limit in the Heart rate menu

The table lists the factory settings for each age group:

| | **0 to 2 years** | 2 to 6 years | >6 years |
|---|---|---|---|
| Min. respiration rate [/min] | 10 | 5 | 4 |
| Lower heart rate limit [/min] | 80 | 60 | 55 |
| Upper heart rate limit [/min] | 220 | 150 | 120 |

**All other settings are not specific to age groups.**

The values set last are retained when VitaGuard® is switched off and when the supply network or batteries fail to provide power.

### 10.3.4 System\ Pre- and Post-alarm time

In the event of an alarm, data for the pre-alarm and post-alarm times set here are stored in addition to the duration of the alarm. These times can be set from 30 to 180 seconds for pre-alarm and from 30 to 250 seconds for post-alarm in steps of ten seconds.

Also the menu item “System\ Interval recording” explained on page 113 records data for the duration of the pre-alarm and post-alarm times.

### 10.3.5 System\ Alarm mute time

In order to allow caregivers to tend to a patient in peace during an alarm, the acoustic alarm signal can be temporarily deactivated with the <Esc> key. Set the Alarm mute time to 30, 60, 90, or 120 seconds as required. The acoustic alarm signal is automatically reactivated after this time.

### 10.3.6 System\ Date/ time

How to change these values is explained in the section “Changing multiple-component settings” on page 109. This is used to set the current date and the current time, e.g. for summer and winter times.

### 10.3.7 System\ Language

**The menu option Language is marked with a flag symbol in the event that you do not understand the set language.**

The submenu Language lets you choose between the languages supported by your monitor version.

### 10.3.8 System\ Analog input 1 + 2

You can activate and deactivate the two analog inputs separately. Both analog inputs have an input range from 0 to 2.5 V. An analog signal at input 1 (when activated) is scanned with 1 Hz and stored, a signal at input 2 is scanned with 32 Hz and stored.

### 10.3.9 System\ Interval recording

The doctor can use Interval recording for specific situations and can set an interval in steps of ten minutes after which monitored data are again stored. After each of these intervals, the monitor stores data for the Pre-alarm and Post-alarm times. The setting 0 min deactivates interval recording.

### 10.3.10 System\ Show PR/ HR

This lets you set whether the Heart rate HR and the Pulse rate PR are displayed simultaneously in View 1 and 2.

## 10.4 Data storage functions

**The function Admit new Patient in the System menu overwrites all the currently stored data and restores the factory settings. If necessary, transfer the data beforehand to a PC.**

The memory contents of VitaGuard® are also retained when the power adapter or batteries fail.

VitaGuard® features the following data storage functions:

- EVENT storage (automatic storage of ALARMS and SILENT ALARMS or MANUAL STORAGE)
- TREND storage (automatically for max 72 hours)
- INTERVAL storage (set in the SYSTEM menu)
- LONG TERM storage (automatically for max eight hours)
- PROTOCOL storage (automatic)

The VitaGuard® display lets you view stored EVENTS and stored TRENDS. LONG TERM and PROTOCOL storage can be evaluated on a PC only. The “Summary of stored signals and data” on page 120 presents the signals and sample rates for the respective memory. The currently utilized memory capacity is shown on the INFO display. The installed memory can store up to 200 events of two minutes each.

## 10.5 EVENT storage

**Please bear in mind that you must wait for the POST-ALARM TIME to expire after an alarm has ended before the current alarm event can be completely stored.**

The time of occurrence and the length of the stored data are stored for every alarm event. The section “Summary of stored EVENTS” on page 117 explains the symbols in the columns for each physiological parameter [⬆ ⬇ (⬆) (⬇) X P].

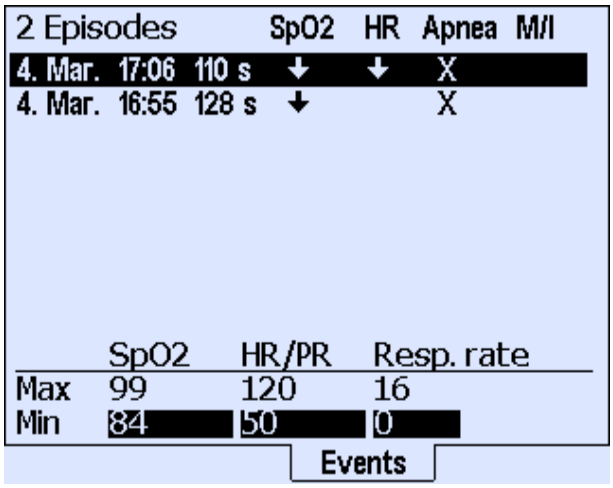



*Fig. 79 List of the stored events*

**M/I** marks the episodes that have been stored via MANUAL STORAGE or INTERVAL RECORDING set in the SYSTEM menu. The minimum and maximum values of the respective physiological parameters are seen at the bottom of the window.

Highlighting an alarm event with the direction keys △ and ▽ and pressing the <Enter> key opens a mask with initial detailed information on this event. Highlighting WAVEFORMS and pressing the <Enter> key displays the waveforms recorded with this event.

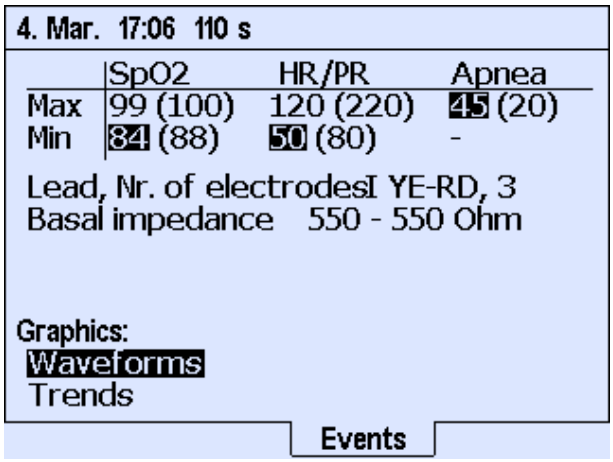



*Fig. 80 Detailed information on a highlighted event*

The black symbol between the displayed times for the start and end of the event marks the section of the stored event currently displayed. The two small vertical bars mark the start and end of the alarm event itself.

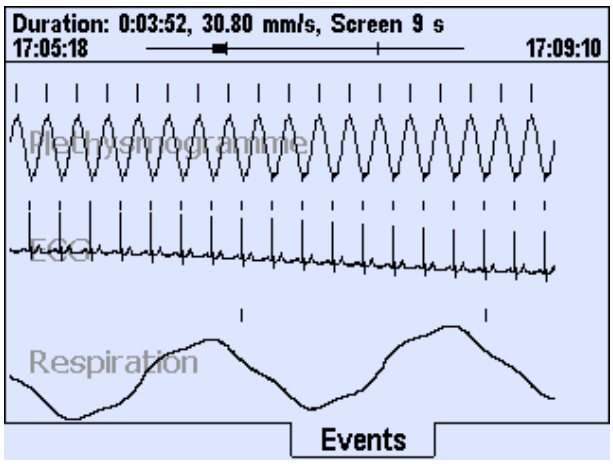



*Fig. 81 Stored waveforms*

Highlighting TRENDS and pressing the <Enter> key displays the TRENDS for $SpO_2$ and heart rate recorded with this alarm.

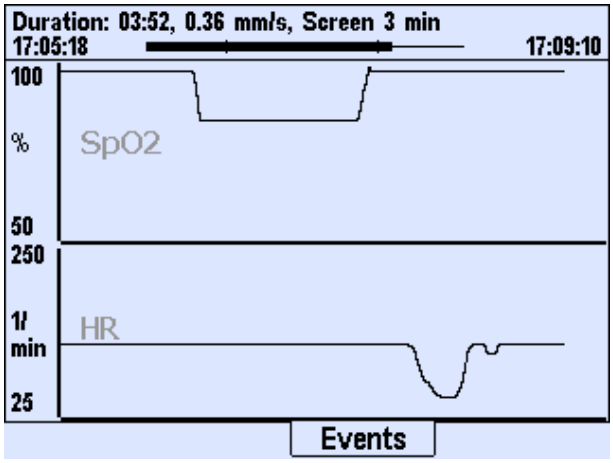



*Fig. 82 Stored trends*

### 10.5.1 Silent alarm limits

The monitor also lets you store signal sequences that are important for evaluating the selected alarm limits. To store these so-called “silent alarms”, activate Silent Alarm limits in the corresponding monitoring menu.

When measurements violate the Silent alarm limits, the current episode is stored without triggering an acoustic or visual alarm. For example, when the Silent lower limit is set higher than the Lower limit in the Heart rate menu, silent bradycardia alarms are stored.

### 10.5.2 Manual data storage or Transmit data

The △ or ▽ key takes you from View 1, 2, or 3 to the Manual data storage or Transmit data menu. In addition to the automatic storage of alarm events, you can also store current data manually. Manual data storage stores data for the set Pre- and Post-alarm times just like in an alarm situation.

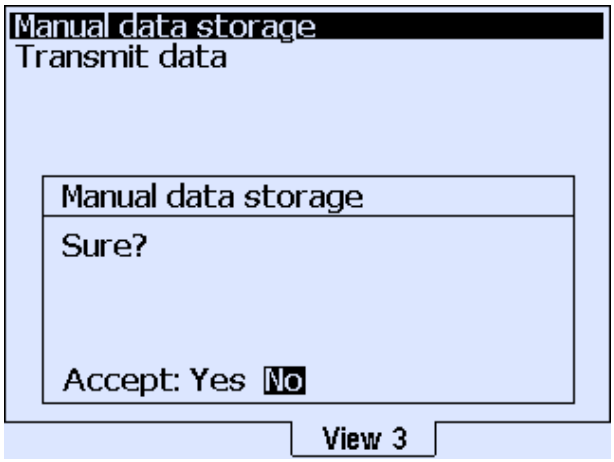



*Fig. 83 View\ Manual data storage*

The AUX socket is used to transmit data via a modem. The setting Since last transmission transfers only those new episodes stored since the last transfer, but no more than twenty.

The setting Last 20 episodes always transfers the last twenty episodes.

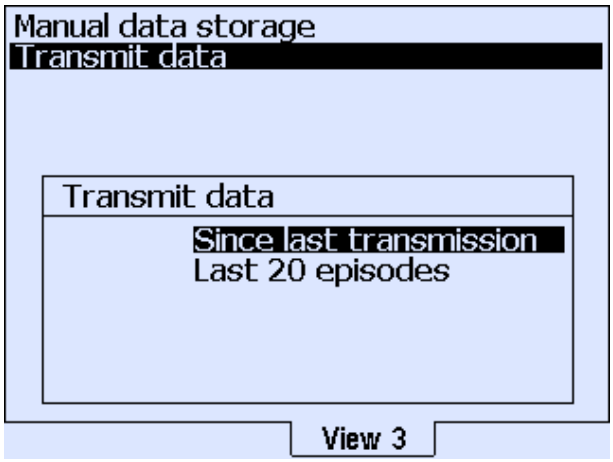



*Fig. 84 View\ Transmit data*

## 10.5.3 Summary of stored EVENTS

The symbols next to the name of each event appear on the EVENTS display in the columns for each physiological parameter following the time and duration of the event.

$SpO_2$ low ⬇ ..... oxygen saturation lower than the set LOWER LIMIT

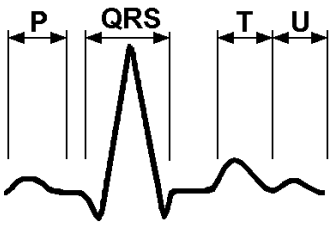
Silent $SpO_2$ low (⬇) ..... measurement lower than the set silent alarm limit

$SpO_2$ high ⬆ ..... oxygen saturation higher than the set UPPER LIMIT

Silent $SpO_2$ high (⬆) ..... measurement higher than the set silent alarm limit

$SpO_2$ drop ⬇ ..... when activated

QRS ⬇ ..... ORS signal amplitude lower than the internal trigger threshold – an QRS alarm is reported when the ECG signal has not been detected, e.g. owing to badly positioned electrodes.




Bradycardia ⬇ ..... heart rate lower than the set LOWER LIMIT

Silent bradycardia (⬇) ... heart rate lower than the set silent LOWER LIMIT

Tachycardia ⬆ ..... heart rate higher than the set UPPER LIMIT

Silent tachycardia (⬆) ... heart rate higher than the set silent UPPER LIMIT

Heart rate drop ⬇ ..... when activated

Heart rate rise ⬆ ..... when activated

Manual **M** ..... manual storage (see “MANUAL DATA STORAGE or TRANSMIT DATA” on page 116)

Interval **I** ..... INTERVAL storage (see “SYSTEM\ INTERVAL RECORDING” on page 113)

Apnea **X** ..... one or more successive apneas

Silent apnea **(X)** ..... one or more short silent apnea phases, shorter than the set APNEA DELAY, but longer than the SILENT APNEA DELAY

Periodic respiration **P** ..... periodic respiration (see section 10.13)

## 10.6 TREND storage

When an episode is highlighted, pressing <Enter> once displays the details, and pressing it a second time the trends.

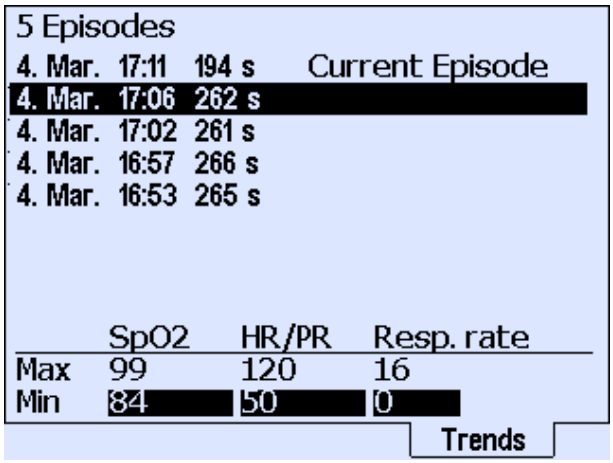

5 Episodes
4. Mar. 17:11 194 s Current Episode
4. Mar. 17:06 262 s
4. Mar. 17:02 261 s
4. Mar. 16:57 266 s
4. Mar. 16:53 265 s
SpO2 HR/PR Resp. rate
Max 99 120 16
Min 84 50 0
Trends

*Fig. 85 List of the episodes stored in the trend memory*

Over a max period of 72 hours the TREND memory stores all of the signals checked in the TREND column of the table on page 120.

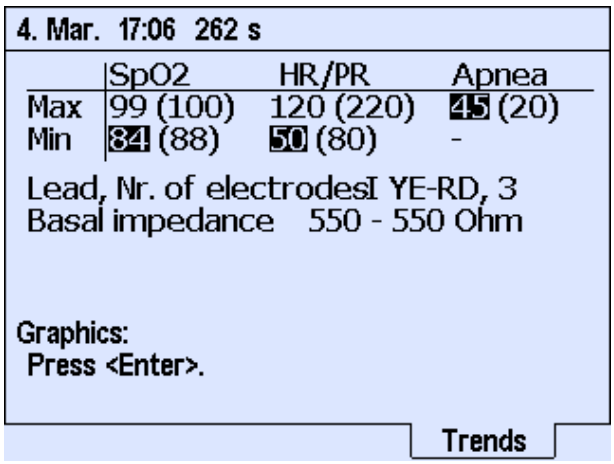

4. Mar. 17:06 262 s
SpO2 HR/PR Apnea
Max 99 (100) 120 (220) 45 (20)
Min 84 (88) 50 (80) -
Lead, Nr. of electrodesI YE-RD, 3
Basal impedance 550 - 550 Ohm
Graphics:
Press <Enter>.
Trends

*Fig. 86 Detailed information on a highlighted trend episode*

## 10.7 LONG TERM storage over eight hours

Independent of alarm events, all signals are stored continuously for a maximum total time of eight hours for subsequent evaluation on a PC (full disclosure). After this period, the oldest data are overwritten.

## 10.8 PROTOCOL storage of operating and device data

The PROTOCOL memory registers e.g. when monitor settings are changed and when the device has been switched on and off. The following changes are stored in PROTOCOL memory:

- Monitor ON/OFF
- $SpO_2$ monitor ON/OFF
- Apnea monitor ON/OFF
- Admission of a new patient
- Changes to SETTINGS PROTECTION

The following data are stored with every change:

- Date and time of the change
- The current monitor settings

**Protocol memory deletes the oldest data when more than 256 entries are stored.**

## 10.9 Summary of stored signals and data

| Data type | Sample rate [Hz] | Alarms | Long term | Trend |
|---|---|---|---|---|
| ECG waveform | 256 | ✔ | ✔ | |
| Current heart rate | 1 | ✔ | ✔ | ✔ |
| Average heart rate for trend deviation | 1 | ✔ | ✔ | ✔ |
| Average heart rate over 1 min | 0.2 | ✔ | ✔ | ✔ |
| Average heart rate over 1 h | 0.2 | ✔ | ✔ | ✔ |
| Average heart rate over 6 h | 0.2 | ✔ | ✔ | ✔ |
| Average heart rate over 12 h | 0.2 | ✔ | ✔ | ✔ |
| Respiration | 128 | ✔ | ✔ | |
| Respiration rate | 1 | ✔ | ✔ | ✔ |
| Basal impedance | 1 | ✔ | ✔ | ✔ |
| Current $SpO_2$ | 1 | ✔ | ✔ | ✔ |
| Average $SpO_2$ for trend deviations | 1 | ✔ | ✔ | ✔ |
| Average $SpO_2$ over 1 min | 0.2 | ✔ | ✔ | ✔ |
| Average $SpO_2$ over 1 h | 0.2 | ✔ | ✔ | ✔ |
| Average $SpO_2$ over 6 h | 0.2 | ✔ | ✔ | ✔ |
| Average $SpO_2$ over 12 h | 0.2 | ✔ | ✔ | ✔ |
| Current pulse rate | 1 | ✔ | ✔ | ✔ |
| Average pulse rate for trend deviation | 1 | ✔ | ✔ | ✔ |
| Average pulse rate over 1 min | 0.2 | ✔ | ✔ | ✔ |
| Average pulse rate over 1 h | 0.2 | ✔ | ✔ | ✔ |
| Average pulse rate over 6 h | 0.2 | ✔ | ✔ | ✔ |
| Average pulse rate over 12 h | 0.2 | ✔ | ✔ | ✔ |
| Plethysmogram | 64 | ✔ | ✔ | |
| Perfusion | 1 | ✔ | ✔ | ✔ |
| Signal IQ | 1 | ✔ | ✔ | ✔ |
| Status graph | 0.1 | ✔ | ✔ | ✔ |
| AUX1 | 1 | ✔ | ✔ | ✔ |
| AUX2 | 32 | ✔ | ✔ | |

## 10.10 Settings in the $SpO_2$ menu (Settings protection Off)

For these settings, Settings protection must be set to Off as explained under "System\ Settings protection On, Limited, Off" on page 91. The possible settings when Settings protection is set to Limited are explained in the section "$SpO_2$ menu – alarm settings (Settings protection Limited)" on page 93.

Factory settings are shown in bold type.

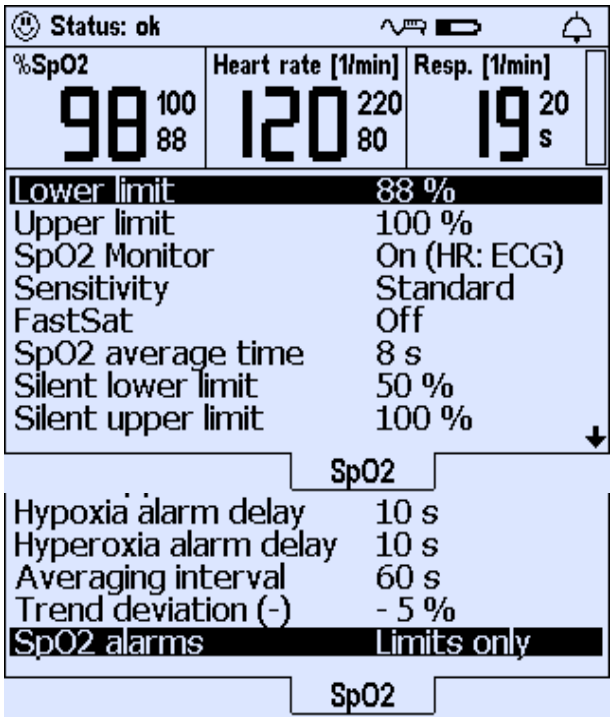



*Fig. 87 Settings in the $SpO_2$ menu*

Sensitivity ..... The Maximum setting is intended for patients with weak blood flow, but its higher sensitivity can hinder the correct detection of a loose $SpO_2$ sensor.
The Minimum setting is intended for patients with good blood flow. This setting utilizes the APOD™ (adaptive probe off detection) algorithm from Masimo Inc., a method that can correctly detect a loose sensor in almost all situations. On the other hand, patients with weak blood flow can trigger technical alarms more often.
In most cases the factory setting **Standard** is recommended.

FastSAT™ ..... When FastSAT™ is **On**, this effectively takes a pulse-to-pulse measurement

suitable for detecting sudden, short desaturations.
When the AVERAGE TIME is set to 4 or 6, FastSAT™ is automatically activated, even when it has been deactivated in this submenu.

AVERAGE TIME ..... 4, 6, **8**, 10, 12, 14, 16 seconds
Here you can view or set the period during which the $SpO_2$ module uses the sensor data to determine each $SpO_2$ and pulse rate value.

SILENT LOWER LIMIT ($SpO_2$) .. **50**, 51 ... 99, 100%
Lower alarm limit for the measured arterial oxygen saturation; when the measured value falls below this limit for longer than the set HYPOXIA ALARM DELAY, a silent alarm is stored.

SILENT UPPER LIMIT ($SpO_2$) .... 50, 51 ... 99, **100**%
As SILENT LOWER LIMIT ($SpO_2$), but with the HYPEROXIA ALARM DELAY.

HYPOXIA ALARM DELAY ..... 1, 2 ... **10** ... 19, 20 seconds
Time between when desaturation is detected ($SpO_2$ too low) and the corresponding alarm is triggered.

HYPEROXIA ALARM DELAY ..... 1, 2 ... **10** ... 19, 20 seconds
As above, but with the UPPER LIMIT for $SpO_2$.

AVERAGING INTERVAL ..... 10, 20 ... **60** ... 110, 120 seconds
The average $SpO_2$ measured over the set interval yields the reference value for calculating the TREND DEVIATION (-).

| | |
|---|---|
| TREND DEVIATION (-) ..... | -3, -4 ...**-10** ... -24, -25%<br>The current $SpO_2$ is compared every second with the average $SpO_2$ measured over the averaging interval. When the current value falls below the average by more than the value set here and when $SpO_2$ ALARMS is set to LIMITS & TRENDS, an alarm is triggered. |
| $SpO_2$ ALARMS ..... | When $SpO_2$ ALARMS is set to **LIMITS ONLY**, alarms are reported only when the measured values violate the set alarm limits. When $SpO_2$ ALARMS is set to LIMITS & TRENDS, alarms are reported when the measured values violate the set alarm limits AND when they deviate from the average $SpO_2$ measured over the set interval. |

## 10.11 Settings in the HEART RATE menu (SETTINGS PROTECTION OFF)

**This menu can refer to PULSE RATE or HEART RATE depending on the settings under $SpO_2$\$SpO_2$ MONITOR. In the example the heart rate is determined with ECG electrodes (the menu bears the caption HEART RATE).**

For this setting, SETTINGS PROTECTION must be set to OFF as explained under "SYSTEM\ SETTINGS PROTECTION ON, LIMITED, OFF" on page 91.

The possible settings when SETTINGS PROTECTION is set to LIMITED are explained in the section "HEART RATE menu – alarm settings (Settings PROTECTION LIMITED)" on page 95.

Factory settings are shown in bold type.

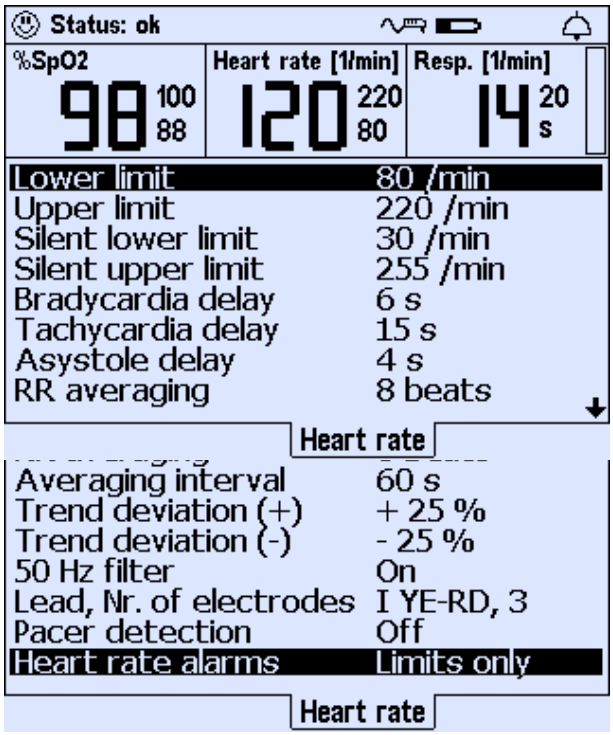



*Fig. 88 Settings in the Heart rate/ Pulse rate menu*

SILENT LOWER LIMIT (HEART) **30**, 35 ... 50 ... 175, 180/min
Lower limit for the heart rate; when the measured value falls below this limit for longer than the set BRADYCARDIA DELAY, a silent alarm is stored.

SILENT UPPER LIMIT (HEART) . 100, 105 ... **255**/min
See SILENT LOWER LIMIT.

BRADYCARDIA DELAY ..... 1, 2, 3, 4, 5, **6** ... 14, 15 seconds
Delay between when bradycardia is detected and the corresponding alarm is triggered.

TACHYCARDIA DELAY ..... 1, 2, 3, 4, 5 ... **15** ... 23, 24 seconds
See BRADYCARDIA DELAY, but for tachycardia.

ASYSTOLE DELAY ..... 1, 2, 3, **4**, 5 ... 14, 15 seconds
See BRADYCARDIA DELAY, but for asystole

RR AVERAGING ..... 2. 4, 6, **8** ... 14, 16 beats
Number of heartbeats used to calculate the heart rate –
the displayed heart rate used to detect alarm conditions is calculated as an average value over the number of heartbeats set here. The greater the value chosen for RR averaging, the slower the system's reaction, particularly in the event of bradycardia, to report an alarm.
When the pulse rate is used instead of the heart rate, the settings for RR averaging have no effect on the measurement.

AVERAGING INTERVAL ..... 10, 20 ... **60** ... 110, 120 seconds
The average heart rate measured over the set interval yields the reference value for calculating TREND DEVIATION (+) and TREND DEVIATION (-).

TREND DEVIATION (+) ..... 5, 10, 15, 20, **25**, 30, 35, 40, 45, 50%
The current heart rate is compared with the average heart rate measured over the averaging interval and an alarm is reported when the set percentage deviation is exceeded. This alarm is reported only when HEART RATE ALARMS is set to LIMITS & TRENDS.

TREND DEVIATION (–) ..... See TREND DEVIATION (+), but the value falls below the set percentage deviation.

50 HZ FILTER ..... Setting the 50 Hz filter to **ON** suppresses interference signals, but also filters out parts of the ECG signal.

LEAD, NR. OF ELECTRODES ..... **I YE-RD, 3 (yellow–red, 3 electrodes)**
II BK-RD, 3 (black–red, 3 electrodes)
III BK-YE, 3 (black–yellow, 3 electrodes)
I YE-RD, 2 (yellow–red, 2 electrodes)
Here you can determine which lead is used with two or three electrodes for detecting the ECG signal (explanations in the following).

PACER DETECTION ..... Activate this for pacemaker patients so that stimulating pacemaker pulses are not mistakenly processed as R waves; explanations can be found under “VitaGuard® and other medical devices” on page 101.

HEART RATE ALARMS ..... – When HEART RATE ALARMS is set to LIMITS ONLY, acoustic alarms are reported when the measured values violate the set alarm limits.
– When HEART RATE ALARMS is set to LIMITS & TRENDS, acoustic alarms are reported when the measured values violate the set alarm limits AND when there is a positive or negative deviation from the average heart rate measured over the set interval.

## 10.12 Changing the ECG lead for signal optimization

**When the used lead frequently causes false heart rate alarms, another lead can be chosen. The default is lead I YE-RD, 3 (yellow–red, 3 electrodes). Signals can be optimized only when the patient is still or sleeping.**

**Bear in mind when optimizing the ECG lead that there must be no changes to the optimized positions of the red and yellow electrodes for detecting the respiration signal. When optimization becomes necessary, only the black electrode must be repositioned.**

**When replacing the electrodes, always choose the same electrode position and color.**

**To avoid too much of a strain on the patient's skin, you can also arrange the electrodes in a small circle around the optimal position.**

By changing the ECG lead you can optimize separately the detection of respiration and heart signals for VitaGuard®.

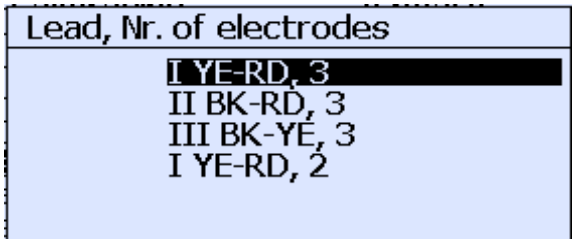



*Fig. 89 Heart rate menu \ "Lead, Nr. of electrodes" submenu*

- I YE-RD, 3 (yellow–red, 3 electrodes)

Both signals, the heart and the respiration signal, are measured between <yellow> and <red>.

- II BK-RD, 3 (black–red, 3 electrodes)

Like lead I, the respiration signal is measured between <red> and <yellow>, the heart signal on the other hand between <black> and <red>.

- III BK-YE, 3 (black–yellow, 3 electrodes)

Like lead I, the respiration signal is measured between <yellow> and <red>, the heart signal on the other hand between <black> and <yellow>.

- I YE-RD, 2 (yellow–red, 2 electrodes)

This lead is used when only two electrodes are to be attached.

Test the quality of the signal from the heart rate monitor with all leads.

When VIEW 1 displays the quality level GOOD for at least one of these leads, further optimization is not necessary.

**The following explanations follow from the section “Determining the optimal electrode configuration” on page 65.**

The electrode arrangement as depicted in Fig. 41 b (on page 66) is the standard Einthoven arrangement and normally yields good results for heart rate monitoring with the (yellow–red) lead.

1 Select the HEART RATE display, and note the amplitude of the displayed ECG signal. Press △ to open the menu, and note the setting for the ECG LEAD, e.g. "I YE-RD, 3”.

2 Select a different ECG LEAD, e.g. “II BK-RD, 3”. Press <Esc> to return to the HEART RATE display, and again note the displayed ECG amplitude.

3 Repeat the procedure for the last setting, i.e. “III BK-YE, 3”.

4 Select from all three leads the one that produces the greatest deflection. It is not important here whether this deflection is negative or positive.

**Select the lead “I YE-RD, 3” when this is one of two leads that have produced approximately equal amplitudes.**

When none of the leads produces a particularly large amplitude you should change the position of the black electrode and repeat the procedure. Carefully reapply the black electrode until you obtain the best signal amplitude.

When you reposition the electrodes, e.g. as depicted in Fig. 41 a), you must again check the ECG amplitude and, by repeating these steps, select the best lead for this new electrode configuration.

## 10.13 Settings in the Respiration menu (Settings protection Off)

For these settings, Settings protection must be set to Off as explained under "System\ Settings protection On, Limited, Off" on page 91. The possible settings when Settings protection is set to Limited are explained in the section "Respiration menu – alarm settings (Settings protection Limited)" on page 98.

Factory settings are shown in bold type.

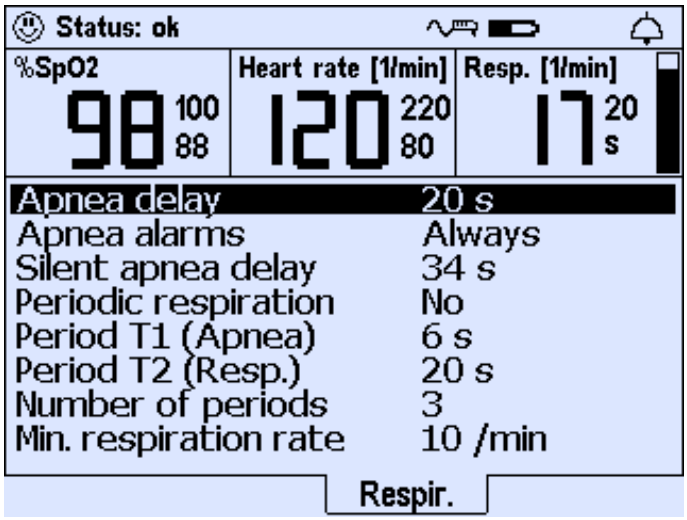



*Fig. 90 Settings in the Respiration menu*

Silent apnea delay ..... 8, 10 ... 22, **34** seconds
Same as Apnea delay, but a silent alarm is stored when exceeded.

Periodic respiration ..... Yes/**No**
This activates the detection of periodic respiration.

**NOTE Activating the monitor for periodic respiration only operates if the age group 0–2 years has been previously selected.**

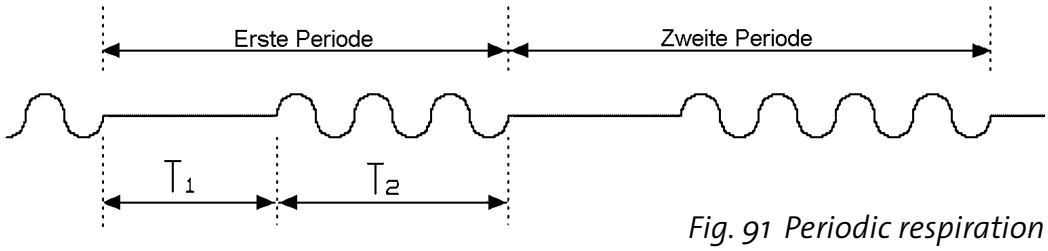



*Fig. 91 Periodic respiration*

Period T1 (Delay) ..... **6**, 8, 10 ... 18, 20 seconds
For the detection of periodic respiration apnea must be longer than T1, but shorter than the set Apnea delay.

PERIOD T2 (RESP.) ..... 4, 6, 8 ... **20** ... 28, 30 seconds
When resumed respiration lasts longer than T2, periodicity is no longer assumed.

NUMBER OF PERIODS ..... 2, **3** ... 5, 6 periods
When the set number of periodic cycles has been reached, the data are stored as a silent alarm.

MIN. RESPIRATION RATE ..... 4, 5, 6 ... 9, **10**/min
VitaGuard® discards signals with a lower rate of occurrence.

**NOTE Changing the min respiration rate to 5/min has an effect only when the age group has been set to 0 TO 2 YEARS under SYSTEM\ ADMIT NEW PATIENT (see "SYSTEM\ ADMIT NEW PATIENT – restoring factory settings" on page 110). For the age group 2 TO 6 YEARS the min respiration rate is fixed at 5/min, for the age group > 6 YEARS at 4/min.**

## 10.14 Combining apnea alarms with heart rate and $SpO_2$ alarms

**When APNOE ALARMS is set to COMBINED, it is important before monitoring that the AVERAGING INTERVAL and the TREND limit(s) are set in the $SpO_2$ and HEART RATE menus.**

A threatening central apnea causes changes to the heart rate and oxygen saturation. Setting APNEA ALARMS to ALWAYS, however, frequently reports an apnea alarm when in fact only the signal amplitudes are too low. Setting APNEA ALARMS to COMBINED helps prevent these false alarms.

Setting APNEA ALARMS to COMBINED starts an observation period of at least 60 s when no respiration has been detected

– for at least 8 s for the age group 0 TO 2 YEARS,

– for at least 12 s for the age group 2 TO 6 YEARS,

– for at least 15 s for the age group > 6 YEARS.

During this observation period the currently measured values for heart rate and oxygen saturation are compared with the average values measured over the set AVERAGING INTERVAL before the event.

When in these sixty seconds neither the heart rate nor $SpO_2$ experiences a negative trend, the monitor assumes a false apnea alarm and does not report it.

## 10.15 Table of operating modes

In the following table the heading "**Menu settings**" is divided into two columns: one for the settings in the RESPIRATION menu and one for the settings in the $SpO_2$ menu. The HEART RATE menu cannot be used to set any values relevant to operating modes. Which of the four vital parameters are monitored and whether apnea monitoring is COMBINED with HEART RATE and $SpO_2$ depend on how the settings are combined. The operating mode marked with **[1]** is the standard monitoring mode for heart rate and respiration as provided by VitaGuard® VG 2100. The operating mode marked with **[2]** is the pulse oximetry monitoring mode as provided by VitaGuard® VG 310.

*The setting "Respiration = COMBINED" takes effect only when the $SpO_2$ monitor is activated.

| Menu settings | | Monitored vital parameters | | | | Operating modes |
|---|---|---|---|---|---|---|
| **Apnea alarms** | **$SpO_2$ monitor** | **$SpO_2$** | **Pulse rate** | **Heart rate** | **Apnea** | **Monitored vital parameters** |
| | | | | | | |
| Respiration = OFF | $SpO_2$ monitor = OFF | No | No | Yes | No | Heart rate |
| Respiration = ALWAYS | $SpO_2$ monitor = OFF | No | No | Yes | Yes | Heart rate and apnea without combined alarm **[1]** |
| Respiration = COMBINED | $SpO_2$ monitor = OFF | No | No | Yes | Yes | Heart rate and apnea without combined alarm* |
| | | | | | | |
| Respiration = OFF | $SpO_2$ monitor = ON (HR:ECG) | Yes | No | Yes | No | $SpO_2$ and heart rate |
| Respiration = ALWAYS | $SpO_2$ monitor = ON (HR:ECG) | Yes | No | Yes | Yes | $SpO_2$, heart rate, and apnea without combined alarm |
| Respiration = COMBINED | $SpO_2$ monitor = ON (HR:ECG) | Yes | No | Yes | Yes | $SpO_2$, heart rate, and apnea with combined alarm |
| | | | | | | |
| Respiration = OFF | $SpO_2$ monitor = ON (PR:Masimo) | Yes | Yes | No | No | $SpO_2$ and pulse rate **[2]** |
| Respiration = ALWAYS | $SpO_2$ monitor = ON (PR:Masimo) | Yes | Yes | No | Yes | $SpO_2$, pulse rate, and apnea without combined alarm |
| Respiration = COMBINED | $SpO_2$ monitor = ON (PR:Masimo) | Yes | Yes | No | Yes | $SpO_2$, pulse rate, and apnea with combined alarm |

# 11 Algorithms and measuring principles

**Knowledge of the following calculation bases is essential if VitaGuard® is to be properly configured.**

## 11.1 Alarm condition and report delays

**As prescribed in the standard IEC 60601-1-8 "General requirements for safety – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems", this section allows the doctor to become familiar with the set and inherent delays for the correct configuration of the alarm limits and monitoring parameters.**

- The alarm *condition* delay is the time from the occurrence of a triggering event on the patient or in the monitor to the decision by the alarm system to confirm an alarm condition.
- The alarm *report* delay is the time between when an alarm condition is detected and when it is reported.
- The alarm *condition* delay and the alarm *report* delay are added to yield the ALARM SYSTEM delay.

The algorithms listed here are based on worst credible cases, i.e. the calculations always return the maximum possible delays.

### 11.1.1 Alarm condition delay for the heart rate

The current heart rate used for detecting alarm conditions is calculated as the average value over a set number of heartbeats (two to sixteen).

The higher the value selected for RR AVERAGING, the longer VitaGuard® needs before the displayed heart rate

$$T_{AC(MAX)}\Big|_{HR} = 60\sum_{n=0}^{N-1}\frac{1}{HR_n}$$

whereby N = AVERAGING

reflects the patient's actual heart rate. When, for example, a value N = 16 is chosen, the actual heart rate is not displayed until after sixteen heartbeats.

The longest alarm condition delay for the heart rate therefore occurs when it is at its lowest. When, for example, the heart rate suddenly drops to thirty beats a minute, a beat is detected every two seconds. When RR AVERAGING is set to 16, a heart rate of thirty is not displayed until after thirty-two seconds.

### 11.1.2 Alarm condition delay for oxygen saturation

An alarm *condition* delay as defined in the standard does not occur when oxygen saturation is monitored. Please observe though the information on alarm *report* delays below.

### 11.1.3 Alarm condition delay for respiration

The impedance pneumography used to monitor apnea must rule out cardiac artifacts as the source of changes to measured impedance. When central apnea has occurred the applied algorithm detects cardiac artifacts after max four heartbeats.

The alarm condition delay for respiration depends in addition on the signal amplifier's recovery time. When in the worst case the amplifier is saturated owing to sudden, violent movements by the patient directly before the occurrence of apnea, the zero line is reached in six seconds. From then, again in the worst case, a period of four beats is needed before any cardiac artifacts can be detected.

$$T_{AC(MAX)}\Big|_{apnea} = 4\left(\frac{60}{HR}\right) + 6 \quad (6 = \text{amplifier's max recovery time in seconds})$$

### 11.1.4 Alarm report delays

The alarm report delays for bradycardia, tachycardia, hypoxia, and hyperoxia can be set within certain limits.

$TA_{(max)}$ for bradycardia: ..... set BRADYCARDIA DELAY + 2 s

$TA_{(max)}$ for tachycardia: ..... set TACHYCARDIA DELAY + 2 s

$TA_{(max)}$ for asystole: ..... set ASYSTOLE DELAY + 2 s

$TA_{(max)}$ for hypoxia: ..... set HYPOXIA ALARM DELAY + 2 s

$TA_{(max)}$ für hyperoxia: ..... set HYPEROXIA ALARM DELAY + 2 s

$TA_{(max)}$ for apnea: ..... 2 s

The purpose of these alarm report delays is to prevent alarms from being reported every time the alarm limits are violated for short times only.

In other words, the maximum alarm report delay corresponds to the maximum set delay. The monitor outputs measurements e.g. to the display every second. The technology's contribution to the total alarm report delay is specified as maximum two seconds overall.

## 11.2 Measuring principle for the $SpO_2$ monitor

The pulse oximeter with Masimo SET® (SET = Signal Extraction Technology®) is based on the following three principles.

1 Oxyhemoglobin (oxygenated hemoglobin) and deoxyhemoglobin (unoxygenated hemoglobin) differ in their absorption of red and infrared light (spectrophotometry).

2 A heartbeat gives rise to a pulse wave that during its cycle changes the volume of arterial blood and therefore its light absorption at the monitoring site (plethysmography).

3 In particular movements also give rise to blood flows that resemble pulse waves and generate interference signals.

Like conventional pulse oximeters, SET® oximeters determine oxygen saturation by directing red and infrared light through tissue and measuring the absorption of light by the blood flow. Light-emitting

diodes (LEDs) serve as light sources and a photodiode as the receiver attached opposite.

Conventional pulse oximetry assumes that all pulsations in the light absorption are caused by the arterial pulse cycle. For this to work, the venous blood in the sensor area must flow completely and therefore constantly through the capillary bed. Conventional pulse oximetry then calculates the ratio of the pulsatile to the mean absorption for both wavelengths (660 nm and 940 nm).

The quotient of the two signals is then formed as follows:

R = S(660)/S(940)

The result R is used to read the corresponding $SpO_2$ value out of an empirically calibrated table mapped in the oximeter software. These tables were drawn up in trials with volunteers who underwent temporary induced hypoxia. During these trials a conventional pulse oximeter was used for the measurements; at the same time, arterial blood was extracted and examined for its oxygen content.

Unlike conventional pulse oximeters, Masimo SET® pulse oximeters assume that not only the arterial, also the venous blood flow varies greatly. Changes to venous light absorption are regarded as a significant source of interference to the pulse signal. The $SpO_2$ module separates the signals for both wavelengths S(660) and S(940) into an arterial signal S and a noise component N that are then used to calculate the ratio R:

S(660) = S1 + N1

S(940) = S2 + N2

R = (S1 + N1) / (S2 + N2)

N1 and N2 are the noise components generated by venous blood.

The DST™ method (discrete saturation transform) isolates and therefore compensates for venous interference components.

The SET® software goes through all the possible values for R (corresponding to $SpO_2$ between 1 and 100%) and calculates the associated interference components. An adaptive noise canceller, or ANC, then takes this value N'(R) to calculate the amplitude of the noise energy, or the so-called output power of the ANC. The result is a DST™ plot (Fig. 92) that exhibits at least the arterial peak. This peak demonstrates the particularly effective noise suppression for the affected $SpO_2$ value when a precisely defined source of signal fluctuations, the arterial pulse cycle, has been identified. Other, also higher peaks can occur during venous fluctuations. Venous blood is saturated less with oxygen, so the peak with the maximum $SpO_2$ value (in the right half of the graph) always corresponds to the arterial oxygen saturation. In Fig. 92 the right peak corresponds to an $SpO_2$ of 97%. The DST calculation is repeated every two seconds on the latest raw data over the preceding four seconds.

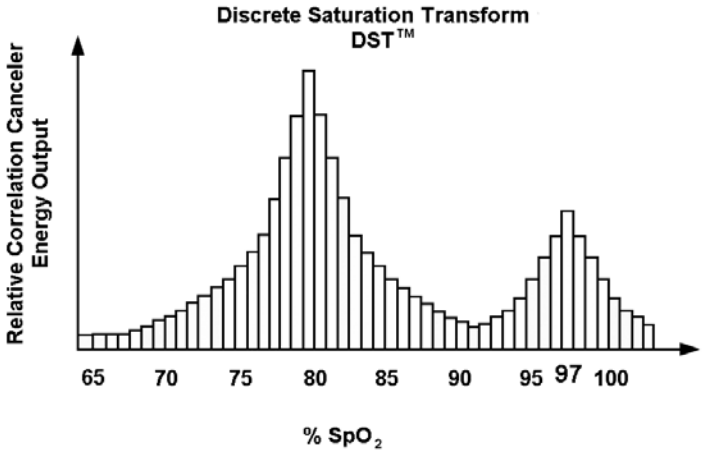



*Fig. 92 DST™ plot: relative noise cancellation as a function of $SpO_2$*

The peak at 80% is caused by venous blood and would, with the conventional method, have completely corrupted the measurement for a false desaturation.

The PERFUSION index (a percentage value) displayed on the monitor is calculated from the electric signal of infrared light captured by the sensor's photodiode. This signal has a constant and a varying component depending on whether the infrared light is absorbed by bone, connective tissue, skin, or pulsatile blood.

The ratio of constant to variable signal component is used to calculate the perfusion index, a value between 0 and 20%. When the PERFUSION index is very small, $SpO_2$ and the pulse rate are no longer monitored. When the SENSITIVITY in the $SpO_2$ menu is set to MAXI-

MUM, the cut-off limit is 0.02%; when set to STANDARD, the limit varies from 0.5 to 0.02% depending on the signal quality.

Further information about FastSat™, APOD™ (adaptive probe off detection), perfusion index, and signal IQ can be found in the white papers at www.masimo.com.

## 11.3 Measuring principle for the heart rate monitor

Every heartbeat, i.e. contraction of the cardiac muscle, generates a myopotential that propagates through the body as an electric signal and that can be measured by two sensing electrodes attached to the body. The graphical depiction of the measured signal is called an electrocardiogram (ECG).

The amplitude and the polarity (positive or negative) of the measured signal depend on both the arrangement of the sensing electrodes and the individual location of the heart.

The signal is very weak (typically one millivolt), so it must be amplified before it can be used to calculate the heart rate.

For this purpose an instrumention amplifier is used in conjunction with filter circuitry. This amplifies the ECG signal and reduces all other unwanted secondary signals, e.g. movement-induced artifacts and electromagnetic interference.

Interference signals can be optimally suppressed, when a third, so-called reference electrode is used. Without this reference electrode, the ECG measuring circuitry must suppress interference signals solely with the aid of filters. When, however, interference signals exceed a certain limit, suppression is no longer possible and the ECG signal can no longer be measured; false alarms are the consequence. The use of a reference electrode is the most common method for effecting an essentially greater suppression of interference.

The adhesive quality and the composition of the gel applied to the electrodes have an additional important effect on ECG measurements. The best results are obtained when the electrodes adhere well. Electrodes that have dried out or adhere badly are unsuitable.

Irrespectively of all interference signals, the heart rate can be measured only when the amplitude of the measured ECG signal itself is large enough to be detected by the monitor. Normally the amplitude of the ECG signal detected on the body surface cannot be influenced and varies from person to person.

The monitor measures the potential difference between the two sensing electrodes. Depending on where the electrodes are attached, the measured signal is strong, weak, positive, or negative. It is even possible that a signal cannot be seen at all. This is the case when the electrodes are inadvertently placed on the same potential line. The propagating signal from a heartbeat can be pictured as contour lines around a hill on a map. When two persons are standing on the same line, the difference in height between these persons is zero. Accordingly, no ECG signal can be measured when the sensing electrodes are placed on such a line on the body surface. To prevent too weak ECG signals from triggering false alarms, it is therefore important that the optimal electrode positions are determined before the start of monitoring.

## 11.4 Measuring principle for the apnea monitor

Unlike the heartbeat, respiration is not accompanied by its own electric signal. A different principle must therefore be adopted for measuring respiration. The most common method is the so-called impedance pneumography. Fluctuations in impedance are caused by both respiratory movements of the thorax and other movements. For this reason, an apnea monitor can function correctly only when the patient is lying still. Here too, the measured signals are very weak and must be amplified. To prevent false alarms wherever possible, it is

very important that the optimal electrode positions are determined before the start of monitoring.

The essential advantage of the described method is that the same electrodes can be used for monitoring the heart rate and respiration.

# 12 Evaluating stored data on a PC

getemed AG has developed the Windows®-based software VitaWin® for evaluating the recorded monitoring data. This software is provided only to doctors and authorized dealers who are or supply VitaGuard® users.

The stored data can be downloaded through the USB (universal serial bus) port to a PC where they can be stored, viewed, and evaluated.

VitaWin® presents each alarm's context based on the signals Respiration, Respiration rate, Basal impedance, ECG, Heart rate, Pulse rate, $SpO_2$, Plethysmogramme, Signal IQ, and Perfusion.

VitaWin® also provides functions for drawing up reports and assessing the patient's monitored data.

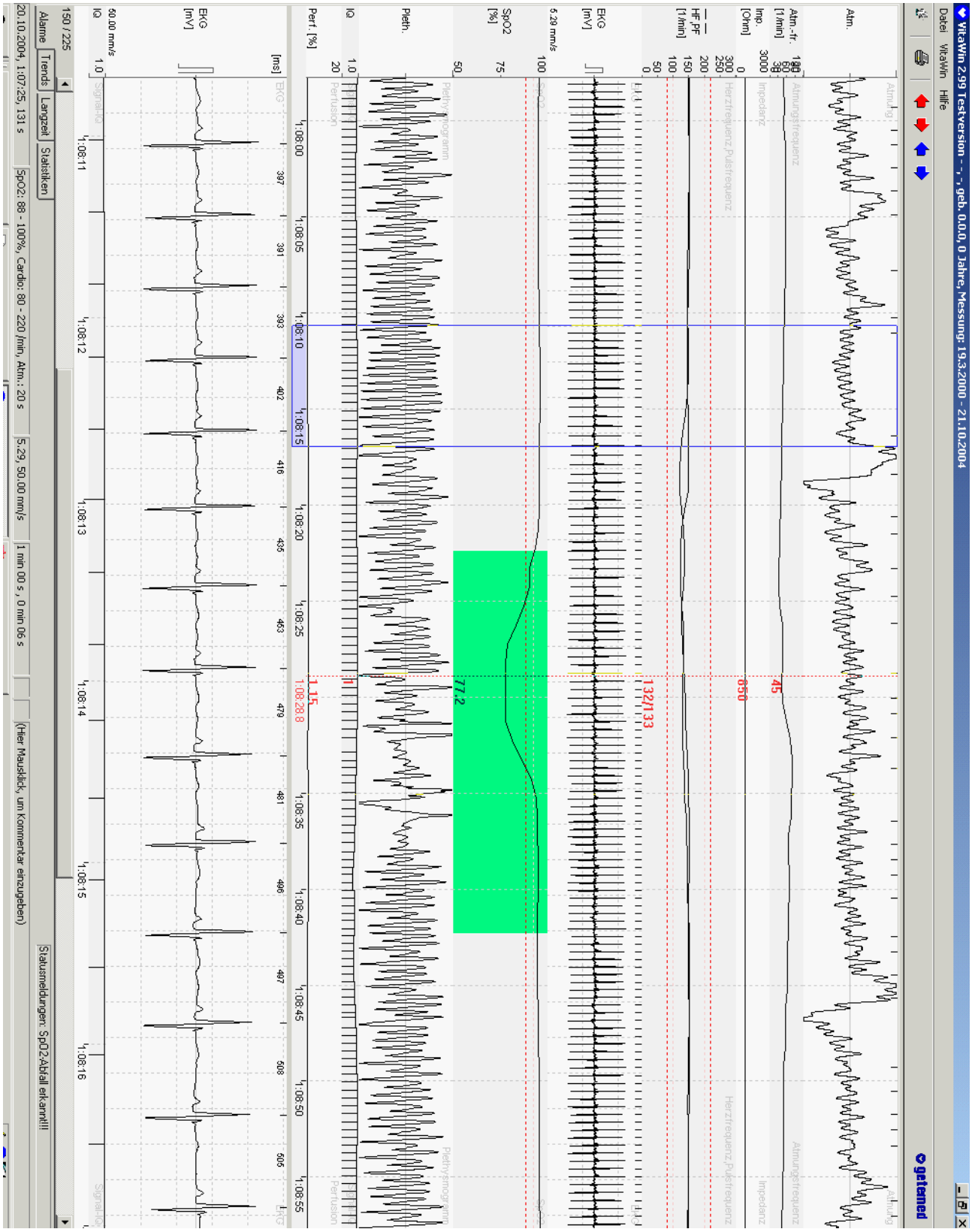


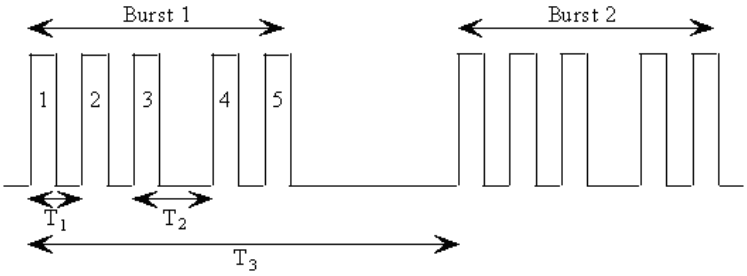

*Fig. 93 VitaWin®\ register “Events in graph form”*

# 13 Specifications

## 13.1 General

| | |
|---|---|
| Weight | approx. 650 g with non-rechargeable batteries<br>approx. 700 g with rechargeable block battery |
| Dimensions | 13.5 x 20.3 x 4.5 cm |
| Non-rechargeable batteries | 4 x 1.5 V (type LR6, AA), alkaline |
| Chargeable block battery | NiMH/4.8 V/2000 mAh |
| Charging time | 6 hours |
| Battery life | e.g. VARTA UNIVERSAL ALKALINE:<br>min 8 hours with $SpO_2$ monitor<br>min 2 days without $SpO_2$ monitor |
| Keys | 6 membrane keys |
| Battery change | displayed message |
| Depleted battery | acoustic alarm |
| Power consumption | < 10 W |
| Power adapter | NA3000-2 power adapter<br>Manufacturer: FRIWO Gerätebau GmbH<br>Type: FW 7555MM/09<br>Output: 9 V, 1500 mA, DC<br>Input: 100–240 V, 50–60 Hz, 400 mA, AC<br>Ingress of protection: IP 40 |

Characteristics of acoustic alarm signals ..... acoustic signals for higher-priority alarms consist of two acoustic sequences of five tones each:




| | | |
|---|---|---|
| Pulse duration | - | 155 ms ± 5 ms |
| Rise and fall time | - | 17 ms ± 3 ms |
| Time between start of pulse 1 and start of pulse 2 | $T_1$ | 215 ms ± 20 ms |
| Time between start of pulse 2 and start of pulse 3 | $T_1$ | 215 ms ± 20 ms |
| Time between start of pulse 3 and start of pulse 4 | $T_2$ | 440 ms ± 20 ms |
| Time between start of pulse 4 and start of pulse 5 | $T_1$ | 215 ms ± 20 ms |
| Time between start of burst 1 and start of burst 2 | $T_3$ | 2 s ± 0.1 s |
| Repeat time for the whole sequence | - | 10 s ± 0.2 s |

acoustic signals for medium-priority alarms consist of three-pulse bursts:

| | |
|---|---|
| Pulse duration | 185 ms ± 5 ms |
| Rise and fall time | 17 ms ± 3 ms |
| Time between start of pulse 1 and start of pulse 2 | 375 ms ± 20 ms |
| Time between start of pulse 2 and start of pulse 3 | 375 ms ± 20 ms |
| Repeat time for the whole sequence | 5.2 s ± 0.2 s |

| | |
|---|---|
| Characteristics of system monitoring signals | pulsating tone of 4 kHz and 1 Hz pulse rate from the sound aperture between the sockets |
| Displays | LEDs and LCD graphic display with 240 x 360 dots |
| Display refresh rate | 1 Hz |
| Expected service life (as per DIN EN ISO 18778) | min seven years |
| Inspection and servicing intervals | getemed AG prescribes safety checks, function checks, and servicing every eighteen months. The next appointment is specified on a label in the battery compartment. |

## 13.2 $SpO_2$ monitor

| | |
|---|---|
| $SpO_2$ display range | 1–100 % |
| Pulse rate range | 25–240/min |
| Perfusion index | 0.02 %–20 % |
| * $SpO_2$ accuracy (calibrated range) for all age groups | – when $SpO_2$ > 70 %, ±3 digits when patient moving or still<br>– when $SpO_2$ < 70 %, unspecified |
| * Pulse rate accuracy for all age groups | ± 3/min when patient still<br>± 5/min when patient moving |
| $SpO_2$ resolution | 1 % |

| | |
|---|---|
| Pulse rate resolution ..... | 1/min |
| Heat emission ..... | max 50 mW (at the LNOP® sensor) |
| Accuracy with weak perfusion (i.e. pulse amplitude > 0.02 % and transmission > 5 %) ..... | $SpO_2$ ±2 digits<br>pulse rate ±3 digits |

* The specified tolerances correspond to a standard deviation of ± 1. This means that within these tolerances, the pulse rate and %$SpO_2$ can be determined for 68% of the population.

## 13.3 Heart rate monitor

| | |
|---|---|
| Heart rate range ..... | 20–270/min |
| Accuracy ..... | ±1 % for heartbeats of similar morphology (averaged over 4 to 16 beats) |
| Sensitivity ..... | 0.2 mV ($\sin^2$ signal with 40 ms width) |
| Input impedance ..... | > 10 MΩ at 10 Hz |

## 13.4 Apnea monitor

| | |
|---|---|
| Max. respiration rate ..... | 120 breaths/min |
| Min. respiration rate ..... | 4, 5, or 10 breaths/min, depending on AGE GROUP setting |
| Alarm quit ..... | 2 breaths within 6 seconds |
| Sensitivity of respiration amplifier ..... | approx. 0.2 Ω/1000 Ω |
| Measuring method ..... | impedance pneumography |

Measuring current frequency 38 kHz

Measuring current ..... < 100 µA

## 13.5 Intervals for calculating average values in the INFO mask

Minute values
for $SpO_2$, HR, PR ..... 1 s

Hour values
for $SpO_2$, HR, PR ..... 30 s

Six-hour values
for $SpO_2$, HR, PR ..... 300 s

Twelve-hour values
for $SpO_2$, HR, PR ..... 300 s

## 13.6 Memory

Storage medium ..... 64 MB compact flash memory card (memory extendable on request)

Nr. of episodes ..... max 200 episodes of two minutes each

Trend ..... max 72 hours

Long term (full disclosure) .. max 8 hours

## 13.7 Ports

USB ..... mini USB port

AUX ..... – modem port (RS232)
– socket for a nurse call system
– socket for an external alarm unit
– socket for two analog inputs from 0 to 2.5 V at 1 or 32 Hz

## 13.8 Miscellaneous

German “Hilfsmittel-nummer” ..... 21.24.02.5005

Calibrating time after activation ..... < 60 s

MPG device class ..... IIb

Device protection class ..... II as per DIN EN 60601-1

Application part ..... BF for $SpO_2$, CF for heart rate and respiration

Ingress protection ..... IP 21

Operating temperature ..... 5–40 °C

Operating humidity ..... 5–95%, non-condensing

Ambient pressure, height above sea level ..... 1060–500 mbar, -304 to +5486 m

*Storage and transport conditions ..... –40 to +70 °C; humidity 15–95%, non-condensing

EMC classification ..... CISPR 11, class B

***Observe the information on the electrodes’ packaging for the storage temperature of electrodes.**

## 13.9 Selection of applied standards

| | |
|---|---|
| IEC 601-1 ..... | Medical electrical equipment – Part 1: General requirements for safety, incl. A 13 |
| IEC 60601-1-1 ..... | Medical electrical equipment – Part 1-1: General requirements for safety – Collateral standard: Safety requirements for medical electrical systems |
| IEC 60601-1-2 ..... | Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests |
| IEC 60601-1-4 ..... | Medical electrical equipment – Part 1-4: General requirements for safety – Collateral standard: Programmable electrical medical systems |
| IEC 62A/422/CDV:2003 (prEN 60601-1-6:2003) ..... | Medical electrical equipment – Part 1-6: General requirements for safety – Collateral standard: Usability |
| IEC 60601-1-8 ..... | Medical electrical equipment – Part 1-8: General requirements for safety – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems |
| IEC 601-2-27 ..... | Medical electrical equipment – Part 2-27: Particular requirements for the safety, including essential performance, of electrocardiographic monitoring equipment |

| | |
|---|---|
| DIN EN 60601-2-49 ..... | Medical electrical equipment – Part 2-49: Particular requirements for the safety of multifunctional patient monitoring equipment |
| DIN EN 865 ..... | Pulse oximeters – Particular requirements |
| prEN ISO 18778 ..... | Infant Monitors – Particular requirements |

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